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**IN THE UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
 PRODUCTS R&D, INC., and
 NORTON (WATERFORD) LTD.,

Plaintiffs,

v.

CIPLA LTD., AUROBINDO PHARMA LLC,
 AUROBINDO PHARMA USA, INC., and
 AUROLIFE PHARMA LLC,

Defendants.

:
 : Consolidated Civil Action No. 20-10172
 : (MCA)(MAH)
 :

:
 : CONFIDENTIAL –
 : SUBJECT TO DISCOVERY
 : CONFIDENTIALITY ORDER
 :

REPORT OF DR. DAVID LEWIS, PH.D.

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I. Background and Qualifications

1. My name is David Lewis, and I am Director of Oz-UK Ltd. (“Oz-UK”) and 3DI Solutions Ltd. (“3DI Solutions”). I have held those positions since July 2015 and April 2008, respectively. Oz-UK and 3DI Solutions are pharmaceutical consulting companies that support industry participants in their efforts to research and develop inhalation products, including metered dose and dry powder inhalers with dose counters or dose indicators. At Oz-UK and 3DI Solutions, I frequently provide companies with advice regarding the formulation, packaging, and design of such devices.

2. I hold three degrees from the University of Essex, including a bachelor’s degree with honors in physics (1989), a master’s degree in chemistry (1991), and doctorate in chemistry (1994). My master’s research focused on the spray characteristics of pressurized packages (i.e., canisters) containing chlorofluorocarbon and hydrocarbon propellant formulations.

3. I have more than twenty-five years’ experience working in the inhalation device industry. Between August 2008 and August 2020, I was Director of Aerosol Science at Chiesi Ltd., UK (“Chiesi”). Chiesi is an international pharmaceutical company that researches and develops drug products and devices. While there, I led Chiesi’s research and development of its Atimos®, Clenil®, Foster®/FostAir®, and Trimbow® inhalation products. My responsibilities included overseeing research and development of both the formulations and their packaging, including the design of the inhalers for those devices. I also oversaw testing of the finished products, including any dose counters or dose indicators. In addition to my work on specific products, I founded Chiesi’s U.K. Research Center in Chippenham, United Kingdom, as the center for excellence for Chiesi’s metered dose inhaler and dry powder products.

4. Between May 1996 and May 2008, I was Head of Hydrofluoroalkane (“HFA”) Programmes at Vectura Ltd. (“Vectura”). Today, Vectura is a British pharmaceutical company

that specializes in researching and developing dry powder and metered dose inhalers. In 1997, Vectura spun off from the University of Bath as a vehicle for commercializing technologies developed at the university. I was one of the key managers involved in overseeing that transition.

5. On numerous occasions, I have provided advice to pharmaceutical companies and research universities regarding the design of metered dose inhalers and/or dose counters, including, among others, Chiesi Farmaceutici S.p.A, Copley Scientific Ltd., Oxford Lasers Ltd., King's College London, Loughborough University, Monash University, University of Bristol, University of Parma, and University of Sydney. Because of my reputation, companies and universities seek my services to assist them in solving problems that their own scientists and engineers cannot.

6. During my career, I have authored more than 130 publications involving inhalation technologies. Representative publications include, among others, Farkas et al., Experimental and Computational Study of the Effect of Breath-Actuated Mechanism Built in the NEXThaler® Dry Powder Inhaler, 533 Int'l J Pharm. 225 (2017); Gavtash et al., Transient Flashing Propellant Flow Models to Predict Internal Flow Characteristics, Spray Velocity, and Aerosol Droplet Size of a pMDI, 52 Aerosol Sci. & Tech. 494 (2017); Mason-Smith et al., Insights into Spray Development from Metered-Dose Inhalers through Quantitative X-Ray Radiography, 33 Pharm. Res. 1249 (2016); Chen et al., High-Speed Laser Image Analysis of Plume Angles for Pressurized Metered Dose Inhalers: The Effect of Nozzle Geometry, 18 AAPS PharmSciTech. 782 (2016); Chen et al., The Influence of Actuator Materials and Nozzle Designs on Electrostatic Charge of Pressurised Metered Dose Inhaler (pMDI) Formulations, 31 Pharm. Res. 1325 (2014); and Lewis, Metered Dose Inhalers: Actuators Old and New, 4 Expert Opinion on Drug Delivery 235 (2007), the last of which I understand the parties to have cited in this litigation. I also hold more than 30 patents covering inhalation technologies.

7. I have served as a referee for Aerosol Science and Technology, which is the official journal of the American Association for Aerosol Research, and I have been asked to serve as an editor or referee for numerous other high-impact journals.

8. My curriculum vitae describing my professional experience, educational credentials, and publications are attached as Exhibit A to my Opening Expert Reports and re-attached as Exhibit A to this report.

9. Based on my experience and qualifications, I consider myself to be an expert in inhalation device technology, including the design of metered dose inhalers and dose counters.

10. Counsel for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, “Teva”) have engaged me in this litigation. I previously submitted two Opening Expert Reports on infringement in this litigation on April 29, 2022. In this report, I provide additional opinions. I am being compensated for my time at a rate of £300.00 GBP per hour, plus expenses. My compensation is not contingent upon the outcome of this litigation.

11. In the previous four years, I have testified by deposition or at trial in European cases involving Chiesi’s Atimos®, Clenil®, Foster®/FostAir®, and Trimbow® products.

12. As stated in my Opening Expert Reports, I have been informed that Teva has asserted the following patents and claims against Defendants Cipla Ltd. (“Cipla”) and Aurobindo Pharma, LLC, Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, “Aurobindo”):

- a. U.S. Patent No. 9,463,289 (the “’289 Patent”), Claims 1-8;
- b. U.S. Patent No. 9,808,587 (the “’587 Patent”), Claims 1-8, 11-22;
- c. U.S. Patent No. 10,086,156 (the “’156 Patent”), Claims 1, 9, 11-13; and

d. U.S. Patent No. 10,561,808 (the “’808 Patent”), Claims 1, 27-28
(collectively, the “Asserted Patents” and “Asserted Claims”).

13. I have been informed that Defendants contend that the Asserted Claims are invalid. I have been informed that Mr. Gregor Anderson has submitted an expert report in this litigation relating to the validity of the Asserted Claims.

14. In forming my opinions, I have considered the materials cited in this report. I have also considered the Asserted Patents, the Asserted Patents’ file histories, the Opening Report of Mr. Anderson, dated April 29, 2022 (and the materials cited therein), the Supplemental Expert Report of Mr. Anderson, dated May 24, 2022 (and the materials cited therein), Defendants’ invalidity contentions (and the materials cited therein); as well as my education, training, and experience.

15. If asked, I will be prepared to present a basic tutorial to explain the terms and concepts related to the opinions set forth in my expert reports, as well as to provide further background on inhalation aerosol drug products and dose counters, the state of the art, the level of skill in the art, and the patents at issue. That tutorial may include demonstrative exhibits and models, including models generated by software.

16. Furthermore, and as noted throughout my expert reports, I will be prepared to present a physical demonstration of the limitations at issue in this case using Teva’s Qvar® HFA or ProAir® HFA products, Defendants’ Abbreviated New Drug Application (“ANDA”) Products, other inhalers or dose counters, or representations of those products. This demonstration may include demonstrative exhibits and models, including models generated by software.

17. In addition to the opinions and bases set forth in my expert reports, my testimony may include responses to facts, arguments, allegations, or references raised by Defendants or their

experts in this litigation. I reserve the right to supplement my opinions if additional information is provided to me or if additional research leads me to conclude that supplementation is necessary.

II. Summary of Opinions

18. The following paragraphs summarize some of my opinions in this matter at a high level. This summary is not meant to limit the opinions expressed below in greater detail, but instead to provide a general overview of the subject matter of my testimony.

19. I have been asked to respond to the Opening Report of Mr. Anderson, dated April 29, 2022, and the Supplemental Expert Report of Mr. Anderson, dated May 24, 2022, in which he opines that the Asserted Claims are invalid.

20. I disagree with Mr. Anderson's opinions that the Asserted Claims of the '289, '587, '156, and '808 Patents are invalid:

- a. In my opinion, the Asserted Claims of the '289, '587, '156, and '808 Patents are not invalid as anticipated for the reasons stated in Mr. Anderson's reports.
- b. In my opinion, the Asserted Claims of the '289, '587, '156, and '808 Patents are not invalid for obviousness for the reasons stated in Mr. Anderson's reports.
- c. In my opinion, Asserted Claim 12 of the '156 Patent is not invalid for indefiniteness for the reasons stated in Mr. Anderson's Opening Report.
- d. In my opinion, the Asserted Claims of the '808 Patent are not invalid for lack of adequate written description of enablement for the reasons stated in Mr. Anderson's Opening Report.

21. Below, I respond to Mr. Anderson's analysis. To be clear, I have only responded to the arguments Mr. Anderson made in his Opening and Supplemental Reports. Should Mr. Anderson be permitted to expand or further supplement his analysis, I reserve the right to offer additional opinions that address any new assertions.

III. Legal Principles

22. I have been asked to apply certain legal principles in forming my opinions. Below, I summarize some of the principles that I have applied in performing my analysis.

A. The Person of Ordinary Skill in the Art

23. As set forth in my Opening Expert Reports, each of the Asserted Patents claims priority to U.S. Provisional Patent Application Nos. 61/345,763 (the “’763 Provisional Application”), filed May 18, 2010, and 61/417,659 (the “’659 Provisional Application”), filed November 29, 2010, and U.S. Patent Application No. 13/110,532 (the “’532 Application”), filed May 18, 2011. The Asserted Patents also name the following individuals as inventors: Declan Walsh, Derek Fenlon, Simon Kaar, Jan Geert Hazenberg, Daniel Buck, Paul Clancy, Robert Charles Uschold, and Jeffrey A. Karg. I have been informed that Mr. Walsh and Mr. Karg have been deposed in this case, and I have reviewed their deposition transcripts.

24. In his Opening Report, Mr. Anderson states that the “earliest possible priority date [for the Asserted Patents] is May 18, 2010, and the earliest possible critical date under 35 U.S.C. § 102(b) is May 18, 2009.” Anderson Opening Rep. ¶ 57. Mr. Anderson bases these dates on the ’763 Provisional Application’s May 18, 2010 filing date. *See* Anderson Opening Rep. ¶ 57.

25. I have reviewed the ’289, ’587, ’156, and ’808 Patents; the ’763 and ’659 Provisional Applications; the ’532 Application; and Teva’s research and development materials. In my opinion, the Asserted Claims of the ’289, ’587, ’156, and ’808 Patents are entitled to a priority date of no later than November 5, 2009. *See, e.g.*, TEVAQVAR-00764323 (ProAir® HFA Design History File); TEVAQVAR-00763343; TEVAQVAR-00763398; TEVAQVAR-00763430; TEVAQVAR-00763520; TEVAQVAR-00763540; TEVAQVAR-00763552 (ProAir® HFA Phase Review Presentations); TEVAQVAR-00465767-892 (Design Files); TEVAQVAR-00771688; TEVAQVAR-00771690; TEVAQVAR-00771691; TEVAQVAR-00771692;

TEVAQVAR-00771693; TEVAQVAR-00771695; TEVAQVAR-00771696; TEVAQVAR-00771697; TEVAQVAR-00771698 (Design Drawings). Alternatively, in my opinion, the Asserted Claims of the '289, '587, '156, and '808 Patents are entitled to a priority date of no later than December 2, 2009. *See, e.g.*, TEVAQVAR-00764323 (ProAir® HFA Design History File); TEVAQVAR-00763343; TEVAQVAR-00763398; TEVAQVAR-00763430; TEVAQVAR-00763452; TEVAQVAR-00763520; TEVAQVAR-00763540; TEVAQVAR-00763552 (ProAir® HFA Phase Review Presentations); TEVAQVAR-00771688; TEVAQVAR-00771690; TEVAQVAR-00771691; TEVAQVAR-00771692; TEVAQVAR-00771693; TEVAQVAR-00771695; TEVAQVAR-00771696; TEVAQVAR-00771697; TEVAQVAR-00771698 (Design Drawings). Alternatively, in my opinion, the Asserted Claims of the '808 Patent are entitled to a priority date of no later than March 16, 2010. *See, e.g.*, TEVAQVAR-00032306; TEVAQVAR-00032308; TEVAQVAR-00032309; TEVAQVAR-00734380; TEVAQVAR-00734383 (Teva Design Documents). Alternatively, in my opinion, the Asserted Claims of the '289, '587, and '156 Patents are entitled to a priority date of no later than May 18, 2010. *See, e.g.*, '763 Provisional Application. Alternatively, in my opinion, the Asserted Claims of the '289, '587, '808, and '156 Patents are entitled to a priority date of no later than November 29, 2010. *See, e.g.*, '659 Provisional Application. Alternatively, in my opinion, the Asserted Claims of the '289, '587, '808, and '156 Patents are entitled to a priority date of no later than May 18, 2011. *See, e.g.*, '532 Application, TEVAQVAR-00027435, at -435-513.

26. Nevertheless, for purposes of my opinions, the differences between these do not affect my conclusions. It does not matter which date between May 18, 2009, and May 18, 2011, is the priority date. My opinions would remain the same based on any priority date within that range. I reserve the right to supplement my opinions in the event that the parties present additional

arguments or evidence (including references published after May 18, 2009) relevant to this issue.

27. As explained below in greater detail, I have been informed that certain issues are evaluated from the perspective of a person of ordinary skill in the art (“POSA”) to which an invention pertains.

28. I have been informed that a POSA is a hypothetical person who may possess the skills, education, and experience of multiple individuals working together as a team. I have been informed that factors for determining the level of ordinary skill in the art may include one or more of the following: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the relevant technology; and (6) the educational level of workers active in the field.

29. In my Opening Expert Reports, I offered the opinion that the POSA for the Asserted Claims as of the priority date would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included one or more individuals with master’s degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor’s degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. The team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices. *See* Lewis Opening Reps. § V.

30. In his Opening Report, Mr. Anderson offers the following definition of the POSA

for the Asserted Patents:

A person of ordinary skill in the art pertaining to the subject matter of Patents-in-Suit, as of the earliest possible effective U.S. filing date of May 18, 2010, would have been a person with a bachelor's degree in pharmaceutical science or a related discipline, and at least 2-3 years of product development experience with design and manufacture of metered dose inhalers. Alternatively, a person of ordinary skill in the art would have a master's degree or Ph.D. in pharmaceutical science, mechanical or medical device engineering, or a related discipline, and at least 1-2 years of product development experience with metered dose inhalers and counter systems. A POSA may have also worked as part of a multi-disciplinary team of scientists in pursuit of developing a pharmaceutical product and drawn upon not only his or her own skills, but also consulted with others of the team having specialized skills.

Anderson Opening Rep. ¶ 58.

31. Mr. Anderson's definition of the POSA is materially identical to the alternative definition that I analyzed in my Opening Expert Reports. *See* Lewis Opening Reps. ¶ 40. As I explained in my Opening Expert Reports, it is unclear to me how that definition of the POSA was derived, and I disagree with it to the extent that it conflicts with my own. Nevertheless, my opinions would not change if I were to assume, contrary to my opinion, that that definition is correct.

32. I reserve the right to supplement my opinions in the event that the parties present additional argument or evidence relevant to this issue.

B. Claim Construction

33. I have been informed that claim construction refers to the process in which the Court determines the legal meaning of a patent's claims. I have been informed that a patent's claims should be construed according to their ordinary and customary meaning in view of the patent's specification and prosecution history, unless the patent defines a claim term, in which case that definition should be applied.

34. As explained in my Opening Expert Reports, I have been informed that the parties have agreed to the following claim constructions. I have applied those constructions in forming my opinions.

<u>No.</u>	<u>Term</u>	<u>Agreed-Upon Construction</u>
1	“canister housing”	“the portion of the inhaler body that is arranged to retain a medicament canister”
2	“inside surface”	“an interior surface”
3	“body”	“the body of the inhaler”
4	“associated with”	“related to”
5	“canister support formation”	“a formation arranged to reduce canister rocking”
6	“actuator”	“A structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component.”
7	“actuator pawl arranged to engage with a first tooth of the ratchet wheel”	“a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel.”
8	“wall surfaces separating the canister receiving portion and the counter chamber”	“wall surfaces of the inhaler body which are substantially perpendicular to the direction of canister movement and which divide the canister-receiving portion and counter chamber”
9	“regulator”	“a structure of the dose counter that modulates motion of the counter display”
10	“regulate motion of the counter display”	“modulate motion of the counter display”
11	“ratchet wheel”	“a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl”
12	“first direction”	“single direction at a time”
13	“main surface of the inner wall”	“inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of

<u>No.</u>	<u>Term</u>	<u>Agreed-Upon Construction</u>
		the movement of the medicament canister when it is pressed downward by the user to expel medicament”
14	“inner wall through which a portion of the actuation member extends”	“an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament”
15	“inner wall”	“an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body”
16	“protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler”	“guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter’s actuator enough to cause unwanted incrementing (or decrementing) of the dose counter”

See Joint Claim Construction Chart 3-5.

35. As explained in my Opening Expert Reports, I have been informed that the parties dispute the meaning of the following claim terms and have proposed competing constructions. I have been informed that the Court has yet to rule on these disputes. Accordingly, I have applied both parties’ constructions in forming my opinions. In my opinion, and as explained in this report, the Asserted Claims are not invalid under either side’s proposed constructions.

<u>No.</u>	<u>Term</u>	<u>Plaintiffs’ Construction</u>	<u>Defendants’ Construction</u>
1	“actuation member” ’289 Patent, claims 1, 3	Plain and ordinary meaning in view of the claims, specification, and	“pin arranged to engage with a medicament canister and effect movement

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
	'587 Patent, claims 1, 3, 11, 12, 13 '156 patent, claims 12	prosecution history. “a component of the dose counter’s actuator that transmits motion from the canister to the actuator”	causing the dose counter to record a count”
2	“[lying or lie] in a common plane coincident with the longitudinal axis X” '289 Patent, claim 1 '587 Patent, claims 1, 12, 21, 22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.	“aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member”
3	“positioned at opposite ends of the inside surface of the main body to face each other” '289 Patent, claim 7 '587 Patent, claims 7, 18	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other”	“positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail”
4	“step[(s)] formed thereon” '289 Patent, claims 5, 8 '587 Patent, claims: 5, 8, 16, 19	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a location of changing width dimension thereon”	“A stepwise increase in the extent to which the support rail extends inwardly”
5	“first reset position” '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history.	“configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
		“a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration”	start configuration, and is just engaged with one of a tooth of the ratchet wheel”
6	“canister fire sequence” '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament”	“process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel.”
7	“canister fire configuration” '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a configuration of the dose counter in which the medicament canister fires medicament”	“configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected”
8	“count configuration” '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history.	“configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
		"a configuration of the dose counter whereby the dosage indicator has indicated a count"	counter has counted one dose"
9	"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"
10	"the body" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "inhaler body" - '156 Patent, 22:64, 67 "dose counter body" - '156 Patent, 22:66	This term is indefinite.
11	"counter display arranged to indicate dosage information" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter that displays information regarding the number of doses remaining"	"structure displaying the number of doses remaining"
12	"first station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history.	"first structure on which the counter is located"

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
		"a first region"	
13	"second station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a second region"	"second structure, separate from the first structure, to which the counter display is moved"
14	"aperture" '289 Patent, claim 3 '587 Patent, claims 3, 13, 20-22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "an opening or open space: hole"	"hole"
15	"separate counter chamber" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a separate chamber of the inhaler in which the dose counter is located"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"
16	"count pawl" '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the ratchet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"

See Joint Claim Construction Chart 6-10.

36. I reserve the right to supplement my opinions in the event that the Court construes these terms or the parties' present additional arguments or evidence relevant to these issues.

C. Anticipation

37. I have been informed that a patent claim is invalid for anticipation if a single prior art reference discloses each and every element of the claim as arranged in the claim. I have been informed that where a prior art reference discloses a broad genus, it will not anticipate a species within that genus unless the genus is defined and very limited in number, such that the POSA could “at once envisage” each member of the genus. Thus, a genus that discloses a large number of species does not anticipate each individual species within the genus.

38. I have been informed that, in certain circumstances, a prior art reference may “inherently” disclose a claim limitation if that limitation is necessarily present in, or is the natural result of the combination of elements expressly disclosed by, that reference. I have been informed that inherency cannot be established by probabilities or possibilities. If a result may or may not result from practice of that reference or teaching, inherency is not established.

D. Obviousness

39. I have been informed that a patent claim is invalid for obviousness if the differences between the invention it claims and the prior art are such that the invention as a whole would have been obvious to the POSA at the time the invention was made. I have been informed that analysis of whether a claim would have been obvious depends on (a) the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, (c) the level of ordinary skill in the art, and (d) any secondary considerations of non-obviousness. I have been informed that the use of hindsight must be avoided because the obviousness of an invention is evaluated from the perspective of the POSA at the time the invention was made. Thus, in conducting an obviousness inquiry, one must be aware of the distortion caused by hindsight bias and must be cautious to avoid reading into the prior art the teachings of the claimed invention at issue.

40. I have been informed that, when a party challenging a patent relies on multiple

references or disclosures to demonstrate that an invention would have been obvious, the challenger must prove not only that the prior art taught or suggested the invention, but also that the POSA would have had a reason to select, modify, and combine the teachings of the prior art to achieve that invention. In other words, the POSA must have had a reason to select, modify, and combine those references or disclosures in the manner claimed by the patent. I have been informed that this includes whether the POSA would have had a reason to select the references and/or disclosures at issue.

41. I have been informed that in determining whether a patent claim would have been obvious, the POSA would have considered the prior art as a whole. I have been informed that, as a consequence, the POSA would consider a reference or disclosure even if it “teaches away” from the invention—that is, if the reference or disclosure would have led the POSA in a different direction from that taken by the patentee and that would have led the POSA to believe that the direction taken by the patentee was unsuitable.

42. I have been informed that, in addition to having a reason to select, modify, or combine the teachings of the prior art, the POSA must have a reasonable expectation of success in doing so. I have been informed that to have a reasonable expectation of success, the POSA must have had a reason to do more than merely vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. I have been informed that in determining whether a patent claim would have been obvious, the POSA would have considered the passage of time from the publication of the allegedly invalidating reference or disclosure. I have been informed that a reference or disclosure that reports success in achieving a particular result may itself indicate a lack of a reason

to modify or combine the reference or disclosure in the manner needed to achieve the claimed invention.

43. I have been informed that, in certain circumstances, a patent claim may be non-obvious where the inventors recognized and solved a problem that the prior art did not recognize. I have been informed that without knowledge of the problem, it would not have been obvious to undertake efforts to solve that problem. I have been informed that even an obvious solution does not render an invention obvious if the problem solved was previously unknown.

44. I have been informed that, in certain circumstances, a combination of elements may have been “obvious to try.” When there was a design need or market pressure to solve a problem and there were a finite number of identified, predictable solutions, the POSA would have had good reason to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Conversely, where the prior art at best gave only general guidance as to the particular form of the claimed invention or how to achieve it, the combination would not have been obvious to try. I have been informed that where the options do not behave predictably, this principle of obvious to try does not apply.

45. I have been informed that a proper obviousness analysis involves an evaluation of any secondary considerations of non-obviousness, also referred to as “objective indicia of non-obviousness.” I have been informed that commonly recognized objective indicia include, among others, evidence of long felt but unsolved needs, failure of others, industry acceptance, and praise. I have been informed that the consideration of such objective indicia guards against hindsight bias and that, in appropriate circumstances, evidence of objective indicia may be determinative of the ultimate question of obviousness. I have been informed that any objective indicia must have a

sufficient nexus to the claimed invention(s); that is, the objective indicia must sufficiently relate to the novel aspects of those invention(s).

E. Written Description

46. I have been informed that patent specification must provide a written description of the invention. I have been informed that a patent claim is invalid for lack of written description support if the specification fails to reasonably convey to the POSA that the inventor(s) had possession of the claimed subject matter as of the filing date. I have been informed that where a patent claims a genus (i.e., a group) of inventions, the specification need not describe every species (i.e., member) within that genus. Instead, the specification need only describe a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that a POSA could visualize or recognize the members of the genus. I understand that the inventor does not need to have physically possessed (e.g., made) the invention to satisfy the written description requirement.

F. Enablement

47. I have been informed that, in addition to providing a written description of the invention, a patent specification must also provide a written description of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable the POSA to make and use the same. I have been informed that a patent claim is invalid for lack of enablement if the specification fails to teach the POSA how to make and use the full scope of the invention(s) without undue experimentation. I have been informed that, in practicing the invention, the POSA would rely on both the specification and his or her knowledge and skill. I have been informed that to satisfy the enablement requirement, the specification need not contain actual working examples or data and the scope of enablement need only bear a reasonable correlation to the scope of the claims.

48. I have been informed that the following illustrative, non-mandatory factors may be

considered when determining if undue experimentation is required: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working examples, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claims. I have considered and applied those factors in reaching my conclusions regarding enablement.

G. Indefiniteness

49. I have been informed that a patent claim must particularly point out and distinctly claim the subject matter that the inventor regards as the invention. I have been informed that a claim is invalid for indefiniteness if the POSA would fail to understand, based on the patent specification, prosecution history, and his or her own knowledge, with reasonable certainty, the scope of the invention. I have been informed that, although a claim must describe the scope of the invention with reasonable clarity, the definiteness requirement takes into account the inherent limitations of language, and some modicum of uncertainty is acceptable. I have been informed that the claims are addressed to the POSA, not to lawyers or to laypersons.

IV. Alleged Prior Art

A. The '406 Publication

50. International Publication No. WO 2007/124406 (the "'406 Publication") is entitled "Dose Counter" and lists Adam J. Stuart, Graham R. Purkins, Rachel Streibig, Stephen J. Howgill, Peter D. Hodson, Richard D. Brewer, and Benjamin J. Holden as inventors.

51. The '406 Publication describes five embodiments of a dose counter for use in inhalers. Paragraphs [0090]-[00116] and Figures 1-11 describe the first embodiment, Paragraphs [00117]-[00134] and Figures 12-20 describe the second embodiment, Paragraphs [00135]-[00159] and Figures 21-30 describe the third embodiment, Paragraphs [00160]-[00170] and Figures 31-40

describe the fourth embodiment, and Paragraphs [00171]-[00182] and Figures 41-47 describe the fifth embodiment. None of these embodiments contains “inner wall canister support formations.” To the contrary, no embodiment, figure, or other description refers to support rails or ribs or any feature that could be considered an “inner wall canister support formation.”

52. The '406 Publication makes clear that the dose counters it discloses do not require that changes be made to the canister housing (a feature the '406 Publication describes as the “actuator”) in order to accommodate those dose counters. For example, the '406 Publication explains that one advantage of its dose counters is that they “require[e] minimal or no changes to the inside and/or outside profile and/or volume of the actuator to accommodate the counter.” '406 Publication, ¶¶ [0012]; *see also* '406 Publication, ¶¶ [0009] (“no or only minimal modification (in shape and/or size) of the housing” needed), [00105] (noting that “it is not necessary to change the external configuration of those actuator housings to accommodate the inventive dose counter”), [00124] (second embodiment), [00151] (third embodiment).

53. Internal dose counters (particularly counters like those in the '406 publication, which are located primarily below the medication canister) pose a risk of disrupting airflow through the device and thereby affecting product performance. The '406 Publication recognizes this concern. *See, e.g.*, '406 Publication, [0009] (noting that compact size of the counter means that it is “less influential on the product performance”), [00105] (reporting that first embodiment “minimize[s] interference and obstruction of the medication spray and airflow paths in the actuator housing”), [00124] (second embodiment), [00151] (third embodiment). This is consistent with the use of the dose counters of the '406 Publication in inhaler bodies that do not contain additional features, like “inner wall canister support formations,” that might alter airflow through the device. *See, e.g.*, '406 Publication, Figs. 3, 16, and 27.

54. The '406 Publication also recognizes the need for simplicity in engineering, particularly when the device in question, such as a dose counter for an MDI, must be mass manufactured inexpensively. To that end, the '406 Publication explains that “[w]hen a dose counter is integrated into the housing for an aerosol inhaler container, it is desirable to minimize its complexity and ease of installation, as well as to provide an arrangement which is as compact as possible, yet which provides a readily reliable and readable medication dosage count to a user.” '406 Publication, ¶ [0006].

55. In my opinion, the '406 Publication suffers from several disadvantages that would have led the POSA away from the dose counters in the '406 Publication as starting points for additional changes. I address those deficiencies in more detail in response to the relevant obviousness theories below. But for clarity, if the POSA set out to add a dose tracking system to an MDI, it is my opinion that the POSA would not have selected any of the dose counters disclosed in the '406 Publication as starting points. However, I also note that the '406 Publication does not identify any particular problems or areas for improvement with respect to the robustness, reliability, manufacturability, accuracy, precision, or unwanted activation of the dose counter it discloses, despite recognizing each of those features as important characteristics of a dose counter. *See, e.g.*, '406 Publication, ¶ [0006]. To the contrary, the '406 Publication presents its counter as a useful solution to those seeking a counter contained within the inhaler housing, which comes with challenges like size, ease of installation, etc. '406 Publication, ¶ [0009]. Accordingly, if (contrary to my opinion), the POSA did select the dose counters of the '406 publication as a starting point for further development, nothing in the '406 Publication would have suggested to the POSA any particular directions for modification. In particular, the POSA would have understood the '406 Publication to instruct that there was no need to alter the canister housing into which its dose

counters were placed. *See, e.g.*, '406 Publication, [0009] (noting that compact size of the counter means that it is “less influential on the product performance”), [00105] (reporting that first embodiment “minimize[s] interference and obstruction of the medication spray and airflow paths in the actuator housing”), [00124] (second embodiment), [00151] (third embodiment). Certainly, nothing in the '406 Publication identifies canister rocking as a problem—the '406 Publication neither recognizes canister rocking as a problem experienced by its dose counters nor does it indicate that its dose counters were engineered to avoid that problem. It follows, of course, that the '406 Publication does not in any way identify canister rocking as a problem that could have adverse effects on counter accuracy.

56. The '406 Publication does not describe in detail the locations of the components of the dose counters that it discloses and does not describe in detail how those locations change over time during operation of those devices. Thus, the POSA could not determine from the '406 Publication the locations of the dose counter components when, for example, a given embodiment reaches the canister fire configuration (i.e., when the medicament canister fires medicament).

B. The '552 Publication

57. International Publication No. WO 2008/119552 (the “'552 Publication”) is entitled “Metered Dose Inhaler” and lists Derek Fenlon as the inventor. The '552 Publication further lists Ivax Pharmaceuticals Ireland as the applicant. The '552 Publication was before the examiner during prosecution of each of the Asserted Patents.

58. Figures 1-4 of the '552 Publication reproduce images from International Patent Publication WO 98/28033, which the '552 Publication describes as a prior art device (to the '552 Publication). *See* '552 Publication, 3:15-6:23, 7:26-25, Figs. 1-4. Figures 5-9 of the '552 Publication describe what the '552 Publication refers to as the “present invention” (i.e., the invention described by the '552 Publication). *See* '552 Publication, 7:26-14:28, Figs. 5-9. In

comparing what it characterizes as embodiments of WO 98/28033 (“WO ’033”) and the present invention of the ’552 Publication, the ’552 Publication states: “The dose counter of the present invention is based on that set out in Figs 3 and 4 described hereinabove except that the pawl 60 has been modified. Modification of the pawl followed an in-depth study of all of the components of the inhaler.” ’552 Publication, 8:7-9. As I explain below in greater detail, the POSA would not understand that statement to mean that the locations of the actuator pawl and the valve stem block in the WO ’033 and the ’552 Publication embodiments were the same. To the contrary, the POSA would understand that the modification of the actuator pawl described in the ’552 Publication could alter the location of the valve stem block.

59. Consistent with the prior art as a whole, the ’552 Publication emphasizes the dangers of undercounting doses relative to overcounting. Thus, the ’552 Publication states: “Clearly, undercounting is particularly undesirable as it can lead to a patient believing that there are more doses left within the inhaler than there actually are.” ’552 Publication, 7:16-24. Based on that disclosure, and in view of the prior art as a whole, the POSA would understand the ’552 Publication to teach away from devices that were biased towards undercounting (i.e., devices in which the dose counter counted *after* the medicament canister fired instead of counting before the canister fired).

60. The ’552 Publication does not describe in detail the relative locations of the actuator pawl and valve stem block and does not describe how those locations change over time during operation of the devices that it discloses. Thus, the ’552 Publication does not describe how the locations of the actuator pawl and valve stem block in the embodiments that it discloses change during the various stages of device operation. And the POSA could not determine from the ’552 Publication where the actuator pawl would be located relative to the valve stem block when, for

example, a given embodiment reaches the “canister fire configuration” (i.e., when the medicament canister fired medicament).

61. In certain embodiments, the '552 Publication states that the dose counter comprises a stock bobbin and split hub. *See, e.g.*, '552 Publication, 9:9-10:8, Fig. 6. With respect to those components, the '552 Publication states: “[T]he stock bobbin 68 . . . is held taught by the action of the split hub 70.” '552 Publication, 9:9-10:8, Fig. 6. In other words, the '552 Publication explains that the split hub resists the movement of the stock bobbin by applying continuous tension; the '552 Publication does not describe the stock bobbin and split hub (or any other combination of components) as modulating the movement of a counter display to incremental movements. The '552 Publication also does not describe how much resistance force the split hub applies to the stock bobbin.

62. Notably, the '552 Publication does not disclose any embodiments comprising a canister housing that has inner wall canister support formations (such as support rails). To the contrary, the '552 Publication provides very little information regarding the features of the canister housing in which the dose counters it describes should be used, aside from nothing that the canister housing has a “stem block” into which the canister’s valve stem fits. '552 Publication, 3:17-19, 25-28. Certainly, nothing in the '552 Publication identifies a problem that inner wall canister support formations would be expected to address. In particular, the '552 Publication neither recognizes canister rocking as a problem experienced by its dose counters nor does it indicate that its dose counters were engineered to avoid that problem. It follows, of course, that the '552 Publication does not in any way connect canister rocking with the presence of a dose counter or adverse effects on counter accuracy.

63. During prosecution of each of the Asserted Patents, the examiner considered the

'552 Publication, but declined to find that it rendered unpatentable the Asserted Claims. *See, e.g.*, '289 Patent, Foreign Patent Documents; '587 Patent, Foreign Patent Documents; '156 Patent, Foreign Patent Documents; '808 Patent, Foreign Patent Documents. I have conducted an independent analysis of the '552 Publication, and in my opinion, the '552 Publication does not render invalid the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the '552 Publication does not render invalid those claims.

C. The '514 Publication

64. International Publication No. WO 03/101514 (the "'514 Publication") is entitled "Dose Indicators and Dispensing Canister-Indicator Assemblies" and lists Eduard Marx as the inventor. The '514 Publication was before the examiner during prosecutions of each of the Asserted Patents.

65. The focus of the '514 Publication is the disclosure of a ring-shaped dose indicator or dose counter that is mounted to the canister and thus moves *with* the canister. *See, e.g.*, '514 Publication, 4:22-23 ("wherein said indicator is arranged to be circumferentially mountable about the dispensing-canister"), 6:4-8 ("Annular dose indicators according to the invention are advantageous in that the indicator can be manufactured independent of the dispensing-canister and the adaptor to provide a self-contained assembly. They can be easily mounted around the dispensing canister by sliding the indicator over the outlet- or container-end of the dispensing canister, as the case may be."), 7:16-24 ("Furthermore dose indicators, in particular the housing, can be advantageously secured to an external surface of the dispensing canister, preferably to an external surface of the container or, if applicable the ferrule of the dispensing canister, to provide a self-contained canister/indicator assembly. The provision of a dispensing-canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the

dispensing canister (e.g. the container of the canister and/or the canister closure means) and above the outlet means of the canister is particularly advantageous, because such an assembly is desirably robust.”), 8:6-14 (“an annular mechanical dose indicator mounted circumferentially about the dispensing-canister and secured to an external surface of the dispensing canister. . . . Preferably the indicator is secured to an external surface of the container. In particular the indicator is desirably secured to the external surface of the container in the vicinity of the first edge of the indicator.”), 8:18-19 (“The indicator is preferably attached to an external surface of the ferrule or the container, more preferably the container.”), 9:19-20 (“an annular mechanical dose indicator arranged to be mounted circumferentially about the dispensing-canister and secured to an external surface of the dispensing canister”), 9:29-30 (“said annular mechanical dose indicator being arranged to be mounted circumferentially about the dispensing-canister and secured to an external surface of the dispensing canister”), 15:11-14 (“The indicator (50) is mounted circumferentially about the dispensing canister, such that the first edge (51) faces towards the closed end (2) of the container and the second edge (52) faces towards the outlet of the dispensing canister, so that at least the outlet member (5) of the canister extends beyond the second edge (52) of the indicator.”), 15:24-28 (“As can be recognized in the preferred embodiment depicted in Fig. 4, the indicator (50) is secured directly to an external surface of the dispensing-canister (10), preferably an external surface of the container (1) (in particular an external surface of the side-wall (9) of the container), more preferably an external surface of the container in the vicinity of the first edge (51) of the indicator.”).

66. Some of the embodiments of the annular system disclosed by the '514 Publication are dose indicators, while others are dose counters. '514 Publication, Title, Abstract, 19:11-13 (“The indicia may be suitably alphabetical, numerical, alphanumeric, or color symbols, providing

a sequential count-up or count-down of dispensed doses or providing a more general indication, such as ‘Full’, ‘Empty’, etc.”), Figure 5 (depicting a display dose information in increments of 10 rather than dose-by-dose). The primary embodiment, and the one depicted in the figures, is a dose indicator. *See, e.g.*, ’514 Publication, Figure 5. But in each of these embodiments, the dose counter or dose indicator is affixed to the canister, creating a canister-indicator assembly that moves together as a unit. *See, e.g.*, ’514 Publication, 7:16-19. In the disclosed embodiments of the ’514 Publication, when the canister is pressed downwards, the canister-indicator assembly moves downwards as a unit, such that a pin that extends upwards from the canister housing enters the dose indicator at a location adjacent to the drive member of the dose indicator, and strikes the drive member on its side, such that the drive member is moved laterally (i.e., in a direction perpendicular to the movement of the canister) and can cause the dose indicator to increment. ’514 Publication, 25:14-30.

67. The ’514 Publication also depicts numerous different canister housing structures, alone or in combination with the annular dose counters or dose indicators it discloses. For example, Figure 2 of the ’514 Publication shows “vertical cross-sectional views of two exemplary, conventional adaptors; an adaptor for a press-and-breathe type inhaler and an adaptor for a breath-actuated inhaler.” ’514 Publication, 11:19-21, Figure 2. These images do not show the integration of an annular dose counter or dose indicator, and are not the same as those configured for use with the annular dose indicator of the ’514 Publication as depicted in, for example, Figures 8 and 10-12. *See, e.g.*, ’514 Publication, 12:8-22, 25:4-22, Figures 8, 10-12. In particular, the POSA would have appreciated that the actuators of the ’514 Publication are altered so that they contain an “actuation pin” extending upwardly from the base of the canister housing, which (when the dose counter and canister assembly moves downwards as the patient actuates the inhaler), passes

through an opening in the dose indicator or counter so that it can interact with certain dose counter components. '514 Publication, Figs. 8a, 8b, 10; *see also* '514 Publication, 25:17-27. The POSA would have appreciated that this actuation pin is an important feature of the inhaler bodies that are utilized with the preferred embodiments of the '514 Publication's annular dose counters, and is a feature that distinguishes those inhaler bodies from inhaler bodies suitable for use with other dose counters. The POSA would not have expected such inhaler bodies to be operable with other dose counters given the presence of the actuation pin.

68. Of the inhaler bodies depicted in the '514 Publication, some have "inner wall canister support formations" in the form of "ribs," while many do not. *See, e.g.* '514 Publication, Figs. 2b, 3, 8b, and 10 (lacking inner wall canister support formations). The '514 Publication certainly does not suggest such ribs are a meaningful feature of the inhaler bodies it discloses—to the contrary, it mentions them only as an optional feature. '514 Publication, 14:17-19 ("One or more ribs (27) may be positioned within the chamber of the cylindrical portion to aid in locating and supporting the container in the correct position."). The '514 Publication does not in any way connect inner wall canister support formations with the accuracy and reliability of the dose counter it discloses, nor does it suggest that rocking of the canister could be caused by introduction of the dose counter—to the contrary, the dose counter of the '514 Publication is affixed to the canister, and the canister thus *cannot* rock due to the presence of the dose counter.

69. I also note that the '514 Publication does not identify any particular problems or areas for improvement with respect to the simplicity, reliability, expense, or obtrusiveness of the indicators and counters it discloses, despite recognizing each of those features as important characteristics of a dose counter. *See, e.g.*, '514 Publication, 3:29-31. Accordingly, if (contrary to my opinion), the POSA did select the embodiments of the '514 Publication as starting points

for further development, nothing in the '514 Publication would have suggested to the POSA any particular directions for modification, and the POSA certainly would not have been motivated to alter the primary feature of those embodiments—namely, an annular dose counter or indicator affixed to the canister, which the '514 Publication touts as advantageous. *See, e.g.*, '514 Publication, 6:4-6 (“Annular dose indicators according to the invention are advantageous in that the indicator can be manufactured independent of the dispensing-canister and the adaptor to provide a self-contained assembly.”), 6:20-23 (“Also because the indicators are positioned about the dispensing-canister, so that the first edge of indicator, which faces towards the closed end of the container, does not extend axially beyond the closed end of the container, a necessary increase in axial dimensions can be avoided, which is particularly advantageous in a portable inhaler.”), 7:21-26 (“The provision of a dispensing-canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure means) and above the outlet means of the canister is particularly advantageous, because such an assembly is desirably robust. Furthermore such an assembly allows for desirable ease in handling and assembly of a complete dispenser.”), 22:8-14 (“The indicator housing (60) is advantageously immovable in relation to the dispensing canister, enhancing overall robustness and handleability of the canister-indicator assembly.”).

70. Indeed, the '514 Publication notes this configuration to be particularly advantageous where the shape of the canister is constricted near the ferrule, because that vacant space can be used for dose counter components and the diameter of the annular counter can be minimized. '514 Publication, 6:25-7:7. The '514 Publication emphasizes the value of confining the shape of the annular dose indicator to the diameter of the canister because it recognizes concerns that larger dose counter or indicators would interfere with airflow or require alterations

to the shape of the canister housing—both problems it recognizes in connection with dose counters located in part below the medication canister. *See, e.g.*, '514 Publication, 3:29 (noting need for “unobstrusive” dose indicator), 7:3-5 (“Containing the dose indicator within the profile of the dispensing canister may also have an additional advantage of interfering less with the airflow through and within a dispenser or adaptor.”), 7:9-14, 8:24-27, 23:4-6, 24:4-9, *see also* '514 Publication, 3:3-8 (describing “devices with dose counters located substantially beneath the container in a region near the outlet means of the dispensing means and near or around the support block of the adaptor” as “disadvantageous in that modification of the adaptor geometry, such as greater dimensions, in the critical region where atomization takes place is generally required.”).

71. During prosecution of each of the Asserted Patents, the examiner considered the '514 Publication, but declined to find that it rendered unpatentable the Asserted Claims. *See, e.g.*, '289 Patent, Foreign Patent Documents; '587 Patent, Foreign Patent Documents; '156 Patent, Foreign Patent Documents; '808 Patent, Foreign Patent Documents. I have conducted an independent analysis of the '514 Publication, and in my opinion, the '514 Publication does not render invalid the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the '514 Publication does not render invalid those claims.

D. The '021 Publication

72. U.S. Patent Application Publication No. 2002/0047021 (the “'021 Publication”) is entitled “Delivery System For a Medicament and Method For the Assembly Thereof” and names Richard Blacker, Daniel K. Engelbreth, and James N. Schmidt as inventors. The '021 Publication was before the examiner during prosecutions of each of the Asserted Patents.

73. The '021 Publication identifies a number of disadvantages to the use of dose counter and dose indicators in MDIs, including that they may “include complex moving parts

which can be difficult to assemble and expensive to manufacture,” may suffer from inaccuracies, may require excessive space to accommodate numerous parts, may impede airflow and medication dispensing. ’021 Publication, ¶ [0006]. But as Mr. Anderson appears to agree, the ’021 Publication does *not* identify an inner wall canister support formation.

74. During prosecution of each of the Asserted Patents, the examiner considered the ’021 Publication, but declined to find that it rendered unpatentable the Asserted Claims. *See, e.g.*, ’289 Patent, U.S. Patent Documents; ’587 Patent, U.S. Patent Documents; ’156 Patent, U.S. Patent Documents; ’808 Patent, U.S. Patent Documents. I have conducted an independent analysis of the ’021 Publication, and in my opinion, the ’021 Publication does not render invalid the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the ’021 Publication does not render invalid those claims.

E. The ’998 Patent

75. U.S. Design Patent No. D416,998 (the “’998 Patent”) is entitled “Inhaler” and names Darren Hodson, Anthony Mayne, and Steven McGugan as inventors.

76. The ’988 Patent is a design patent—it consists of five pages containing eight drawings of an “ornamental design for an inhaler,” but it does not explain the purpose, function or utility of any feature of these designs. Indeed, aside from the cover page and figure numbers, it contains no text whatsoever. The “Description” of the figures indicates that figures 1-8 show different perspectives of the same inhaler.

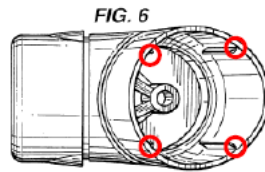
77. Mr. Anderson relies on the ’998 Patent because, he asserts, it discloses a canister housing design that includes “inner wall canister support formations” in the form of ribs, and argues that the ’998 Patent suggests “inner wall canister support formations” “were essentially ubiquitously used in MDIs.” *See, e.g.*, Anderson Opening Rep., ¶¶ 169, 247. He states that “[t]he importance of inclusion of ribs is evidenced by at least a half dozen exemplary references pre-

dating the earliest priority date of the Asserted Patents, each of which discloses the use of ribs in inhalers.” *See, e.g.*, Anderson Opening Rep. ¶¶ 170, 248. He also asserts that the ’998 Patent discloses support rails with “a step formed thereon,” and that the POSA “would have been motivated to select or modify ribs to include tapered or stepped designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve, and to improve tolerance control, fit, and function.” Anderson Opening Rep. ¶¶ 176, 254.

78. I do not agree that the ’998 Patent supports Mr. Anderson’s contentions. As I explain in more detail below where relevant to Mr. Anderson’s obviousness theories, I disagree that support rails were “essentially ubiquitous” as of the priority date. Certainly, I disagree that the five images of a single inhaler design could support such an inference (even when combined with five other, isolated references that contain figures that also show support rails). As I explain below, the prior art and the body of marketed inhalers (both as of the priority date and today) are replete with far more than six examples of inhalers that do not contain support rails. *Infra* Section V.

79. Furthermore, the ’998 Publication is completely silent as to the benefits, if any, of the features Mr. Anderson identifies as “inner wall canister support formations” and so does not teach the what purpose they serve in the context of this particular device. (Indeed, I am informed that the features disclosed in a design patent need only be ornamental and do not have to serve any purpose at all.) Certainly, the ’998 Publication does not suggest that these ribs are intended to “locate the container, and provide an annular passageway to draw air using the mouthpiece,” Anderson Opening Rep. ¶¶ 169, 247. To the contrary, Mr. Anderson suggests that the ribs taught to perform such a function in the prior art were “four equally spaced ribs,” Anderson Opening Rep. ¶¶ 169, 247 (citing Lewis 2007, at 236, CIPLA-BDI_0184749). The ’998 Patent does not depict

four equally spaced ribs—from the eight images it includes, I can discern only two structures that correspond to “ribs”—Mr. Anderson has circled two additional features in the annotated version of Figure 6 he provides below, but I do not agree that this drawing is clear enough to discern whether the structures he identifies on the left side of Figure 6 of the ’998 Patent in paragraphs 169 and 247 of his Opening Report are also “inner wall canister support formations,” let alone whether they “extend[] longitudinally along an inside surface of the main body,” nor whether they contain one or more steps, nor whether they meet any of a number of other structural limitations on the inner wall canister support formations present in various Asserted Claims.



'998 Patent

(1999)

80. There is no canister and no valve depicted in the ’998 Patent, and it is not at all apparent from its disclosure—which contains absolutely no information about the material of which the inhaler depicted is made, nor the dimensions of any of its components—that what Mr. Anderson identifies as “ribs” are configured to “prevent accidental opening of the valve” or “unwanted gassing of the canister,” nor to facilitate insertion of the (undepicted) canister, nor “aid in control of tolerances, allowing for more accurate counting when dose counters are included in the device.” Anderson Opening Rep. ¶ 169. I do not agree with Mr. Anderson that the POSA would have interpreted the disclosure of the ’998 Patent to teach such things, nor that the disclosure of the ’998 Patent would have given the POSA reason to include rails like those depicted in Figure 6 in an altogether different inhaler for any of these reasons (let alone an inhaler that included a

dose counter). I note that the '998 patent does not depict or otherwise suggest the presence of a dose counter, and thus cannot suggest anything at all about the relationship between any inner wall canister support formations and any features of an undisclosed dose counter.

F. The '950 Publication

81. U.S. Patent Application Publication No. 2002/0078950 (the "'950 Publication") is entitled "Reservoir Pressure System For Medicament Inhaler" and lists David O'Leary as the inventor. The '950 Publication was before the examiner during prosecution of each of the Asserted Patents.

82. Mr. Anderson opines that the '950 Publication anticipates and/or renders obvious the '808 Patent. Mr. Anderson is mistaken. As I set out below in response to Mr. Anderson's obviousness theories, the '950 Publication fails to teach, suggest, or disclose a regulator that modulates the motion of the counter display to incremental movements. Nor does the '950 Publication provide any reason to modify a dose counter so that it regulates the counter display to incremental movements. As such, the claimed inventions in the '808 Patent is neither anticipated nor rendered obvious in light of the '950 Publication.

83. During prosecution of each of the Asserted Patents, the examiner considered the '950 Publication. *See, e.g.*, '289 Patent, U.S. Patent Documents; '587 Patent, U.S. Patent Documents; '156 Patent, U.S. Patent Documents; '808 Patent, U.S. Patent Documents. The examiner declined to find that the '950 Publication rendered unpatentable the '289, '587, or '156 Patents. With respect to the '808 Patent, the Patent Trial and Appeal Board ("Board") determined that the '950 Publication did not render invalid the '808 Patent. *See* '808 Patent File History, Board Decision (Sept. 20, 2019). Among other things, the Board found that the evidence did "not adequately support the . . . determination that [the '950 Publication's] device is capable" of regulating the motion of the counter display to incremental movements. '808 Patent File History,

Board Decision (Sept. 20, 2019). In addition, the Board determined that the POSA would not have “reached a regulator capable of regulating motion in the manner claim 1 [of the ’808 Patent] recites based upon the teachings of [the ’950 Publication] or otherwise.” ’808 Patent File History, Board Decision (Sept. 20, 2019). I have conducted an independent analysis of the ’950 Publication, and in my opinion, the ’950 Publication does not render invalid the Asserted Claims. The fact that the examiner and/or the Board made the same determinations as to the Asserted Claims provides further evidence that the ’950 Publication does not render invalid those claims.

84. In addition, I note that the ’950 Publication, despite disclosing a dose counter and a canister housing, does not once mention “inner wall canister support formations” nor any structure that could be an “inner wall canister support formation.” This omission reinforces my opinion that such features were not ubiquitous in the prior art, nor had the prior art appreciated that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy.

G. The ’008 Publication

85. U.S. Patent Application Publication 2006/0289008 (the “’008 Publication”) is entitled “Dispenser with Doses’ Counter” and names Paul Kenneth Rand, Peter John Brand, and James William Godfrey as inventors.

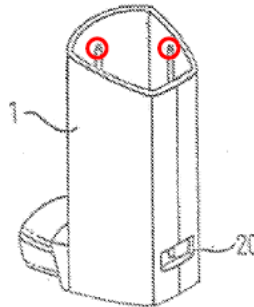
86. Mr. Anderson asserts that the ’008 Publication discloses a canister housing design that includes “inner wall canister support formations” in the form of ribs, and argues that the ’008 Publication suggests, in combination with other references, that “inner wall canister support formations” “were essentially ubiquitously used in MDIs.” *See, e.g.*, Anderson Opening Rep. ¶¶ 169, 247. He states that “[t]he importance of inclusion of ribs is evidenced by at least a half dozen exemplary references pre-dating the earliest priority date of the Asserted Patents, each of which discloses the use of ribs in inhalers.” *See, e.g.*, Anderson Opening Rep. ¶¶ 170, 248. He

also asserts that the '008 Publication discloses support rails with “a step formed thereon,” and that the POSA “would have been motivated to select or modify ribs to include tapered or stepped designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve, and to improve tolerance control, fit, and function.” Anderson Opening Rep. ¶¶ 176, 254.

87. I do not agree that the '008 Publication supports Mr. Anderson's contentions. As I explain in more detail below where relevant to Mr. Anderson's obviousness theories, I disagree that support rails were “essentially ubiquitous” as of the priority date. *Infra* Section V. Certainly, I disagree that the '008 Publication could support such an inference (even when combined with five other, isolated references that contain figures that also show support rails). As I explain below, the prior art and the body of marketed inhalers (both as of the priority date and today) are replete with far more than six examples of inhalers that do not contain support rails. *Infra* Section V.

88. Furthermore, the '008 Publication does not suggest that “inner wall canister support formations” are a meaningful aspect of its disclosure. There are four figures in the '008 Publication that depict inhaler bodies—only one of these four depict features that could be interpreted as “inner wall canister support formations.” *Compare* '008 Publication, Figs. 1, 8 9 *with* '008 Publication, Fig. 7. Indeed, in the single depiction of a canister housing in the '008 Publication in which Mr. Anderson identifies a feature he believes to be an inner wall canister support formation, the '008 Publication viewed that feature as so unimportant to the function of the device that it did not even receive a label. I have reproduced Mr. Anderson's annotated version of Figure 7 of the '008 Publication below from paragraph 176 of his report—as is plain, no label is attached to the features Mr. Anderson suggests are “inner wall canister support formations.” At best, the '008 Publication describes “inner wall canister support formations” as an optional feature of inhaler bodies. *See*

'008 Publication, ¶ [0045] (explaining with respect to Figure 1 that “[s]pacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”). The fact that the '008 Publication either omits spacer rails from its images or fails to label them when included would have suggested to the POSA that inner wall canister support formations had no bearing on dose counter positioning or accuracy.



'008 Publication

(2006)

89. The only purpose the '008 Publication identifies for support rails is to “hold the external surface of the container . . . spaced from the internal surface of the housing.” '008 Publication, ¶ [0045]. This purpose is utterly unrelated to the dose counter that features prominently throughout the rest of the '008 Publication’s disclosure, and would not have suggested to the POSA seeking to introduce a dose counter or dose indicator into an MDI that support rails were a significant feature of canister housing design, let alone that their positioning should be considered in connection with the placement of a dose counter. Indeed, there is no image in the '008 Publication that depicts a “spacer rib” in the same inhaler as a dose counter, let alone makes clear that a particular configuration of spacer rails and dose counter features is important, and there is no description in the '008 Publication that connects the presence or absence of spacer ribs with the presence or absence of a dose counter. Certainly, Figure 7 of the '008 Patent does not suggest that either of the two support rails Mr. Anderson identifies should bear a particular special

relationship to any component of the dose counter disclosed in the '008 Publication. To the contrary, it is plain that the inventors listed on the face of the '008 Publication did not appreciate that the introduction of a dose counter could introduce canister rocking by virtue of the canister's interaction with an actuation member of the dose counter, nor that such rocking could have a negative impact on dose counter performance. That realization was made for the first time by the named inventors of the Asserted Patents.

90. I also disagree with Mr. Anderson that the 008 Publication supports his suggestion that “the inclusion of a dose counter or dose indicator” was a feature “shared by nearly all modern MDIs.” Anderson Opening Rep. ¶ 52. I explain my disagreement more fully in Section V, below, but suffice it to say that the identification of a handful of prior art references, including the '008 Publication, that allegedly disclose the incorporation of a dose counter or dose indicator into an MDI does not suggest that such features were ubiquitous, and it incorrectly conflates dose indicators with dose counters, the former of which were more common. To the contrary, the availability of prior art references allegedly teaching the use of dose counters or indicators in MDIs as of the priority date, in combination with the dearth of marketed MDIs containing such dose counters as of the priority date, amply demonstrates the difficulty in designing such devices-. *See, e.g.,* Lewis Opening Reps. §§ IX.A.1-2, B, *infra* Section V.

H. The '822 Patent

91. U.S. Patent No. 4,817,822 (the “'822 Patent”) is entitled “Indicating Device” and names Paul K. Rand, Carole A. Osterweil, and Robert E. Newell as inventors.

92. The '822 Patent discloses an “indicating device” for use in an inhaler. In particular, it discloses dose indicator embodiments as preferable. *See, e.g.,* '822 Patent, 15:17-34 (“Any suitable markings may be employed, though preferably not letters, numbers or like characters which require to be read. For example, the rack can be marked with different colours of different

portions so that, for example, when a red portion is displayed through the window, the patient will know that a new aerosol container must be obtained. In other alternatives, however, the indicator rack may be marked with numbers to indicate the proportion of the contents still remaining or the number of doses dispensed from or remaining in the aerosol container. In a convenient arrangement, the markings on the indicator rack indicate that the aerosol container is empty after a predetermined number of doses, for example 200, have been dispensed, this predetermined number being less than the number of doses with which the container has been charged, say 220, so as to allow for a margin of error.”).

93. Mr. Anderson relies on the statement in the '822 Patent that “[s]pacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1” to argue that the '822 Publication suggests, in combination with other references, that “inner wall canister support formations” “were essentially ubiquitously used in MDIs.” *See, e.g.*, Anderson Opening Rep. ¶¶ 169, 247. He states that “[t]he importance of inclusion of ribs is evidenced by at least a half dozen exemplary references pre-dating the earliest priority date of the Asserted Patents, each of which discloses the use of ribs in inhalers.” *See, e.g.*, Anderson Opening Rep. ¶¶ 170, 248. He also asserts that the '822 Publication discloses support rails with “a step formed thereon,” and that the POSA “would have been motivated to select or modify ribs to include tapered or stepped designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve, and to improve tolerance control, fit, and function.” Anderson Opening Rep. ¶¶ 176, 254.

94. I do not agree that the '822 Patent supports Mr. Anderson’s contentions. As I explain in more detail below where relevant to Mr. Anderson’s obviousness theories, I disagree that support rails were “essentially ubiquitous” as of the priority date. *Infra* Section V. Certainly,

I disagree that the '822 Patent could support such an inference (even when combined with five other, isolated references that contain figures that also show support rails). As I explain below, the prior art and the body of marketed inhalers (both as of the priority date and today) are replete with far more than six examples of inhalers that do not contain support rails. *Infra* Section V.

95. Furthermore, the '822 Patent does not suggest that “inner wall canister support formations” are a meaningful aspect of its disclosure. There are eight figures in the '822 Patent that depict inhaler bodies and aspects of the dose indicating mechanism described by the '822 Patent. None of these eight Figures show inner wall canister support formations in the inhaler bodies, and Mr. Anderson has not identified any such disclosure. Indeed, the one mention of “spacer ribs” in the '822 Patent states that such ribs are not shown in Figure 1. '822 Patent, 3:11-14 (“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”). The fact that the '822 Patent omits spacer rails from its images and describes them only as optional would have suggested to the POSA that inner wall canister support formations had no bearing on dose indicator or counter positioning or accuracy.

96. The only purpose the '822 Patent identifies for support rails is to “hold the external surface of the container . . . spaced from the internal surface of the housing.” '822 Patent, 3:11-14. This purpose is utterly unrelated to the dose indicator/counter that features prominently throughout the rest of the '822 Patent’s disclosure, and would not have suggested to the POSA seeking to introduce a dose counter or dose indicator into an MDI that support rails were a significant feature of canister housing design, let alone that their positioning should be considered in connection with the placement of a dose indicator or dose counter. There is no image in the '822 Patent that depicts a “spacer rib” in the same inhaler as a dose indicator or dose counter, let

alone any disclosure that makes clear that a particular configuration of spacer rails and dose indicator or counter features is important, and there is no description in the '822 Patent that connects the presence or absence of spacer ribs with the presence or absence of a dose indicator or counter. To the contrary, it is plain that the inventors of the '822 Patent did not appreciate that the introduction of a dose indicator or counter could introduce canister rocking by virtue of the canister's interaction with an actuation member of the dose indicator or counter, nor that such rocking could have a negative impact on dose indicator or counter performance. That realization was made for the first time by the named inventors of the Asserted Patents.

97. I also disagree with Mr. Anderson that the '822 Patent supports his suggestion that “the inclusion of a dose counter or dose indicator” was a feature “shared by nearly all modern MDIs.” Anderson, ¶ 52. I explain my disagreement more fully in Section V, below, but suffice it to say that the identification of a handful of prior art references, including the '822 Patent, that allegedly disclose the incorporation of a dose counter or dose indicator into an MDI does not suggest that such features were ubiquitous, and it incorrectly conflates dose indicators with dose counters, the former of which were more common. To the contrary, the availability of prior art references allegedly teaching the use of dose counters or indicators in MDIs as of the priority date, in combination with the dearth of marketed MDIs containing such dose counters as of the priority date, amply demonstrates the difficulty in designing such devices. I addressed such considerations in more detail in my Opening Report in connection with objective indicia of non-obviousness and below. *See, e.g.,* Lewis Opening Reps. §§ IX.A.1-2, B, *infra* Section V

98. I also disagree with Mr. Anderson's reliance on the '822 Patent in service of an alleged distinction between “tape-based dose counters” and “gear-based dose counters.” *See* Anderson Opening Rep. ¶¶ 53-54. In my opinion, this distinction is not meaningful and the POSA

would not have viewed mechanical dose counters and dose indicators as falling into these two distinct camps. Rather, the POSA would have understood that mechanical dose counters, like other mechanical devices, used a variety of mechanisms to display information and that those mechanisms could be adapted for use in a variety of different inhalation products.

I. The '066 Patent

99. U.S. Patent No. 7,407,066 (the "'066 Patent") is entitled "Dosage Counting Devices" and lists Tianhong Ouyang and Geoff Brace as inventors. Contrary to its title, the embodiment depicted in the Figures of the '066 Patent is a dose indicator, not a dose counter, as it depicts dose information only in increments of 10, not dose-by-dose. *See, e.g.*, '066 Patent, 2:49-55, Figure 2 (showing "marked indicia 45 in the form of numerals" and listing only 50, 40, 30, 20, and 10).

100. Mr. Anderson cites lines 32-34 of column 2 of the '066 Patent in support of his assertion that "a series of ribs" have been a common feature "in MDI inhalers for decades." Anderson Opening Rep. ¶ 50. I do not agree. The '066 Patent simply provides one example of a canister housing that contains ribs—it does not suggest (alone or in combination with the other references Mr. Anderson has selected to demonstrate the presence of ribs) that all or even most MDIs have included ribs for decades. As I explain in more detail where relevant to Mr. Anderson's obviousness theories, I disagree that support rails were "essentially ubiquitous" as of the priority date. *Infra* Section V. The prior art and the body of marketed inhalers (both as of the priority date and today) are replete with examples of inhalers that do not contain support rails. *See, e.g.*, Lewis Opening Reps. §§ IX.A.1-2, B, *infra* Section V.

101. I also disagree with Mr. Anderson that the '066 Patent supports his suggestion that "the inclusion of a dose counter or dose indicator" was a feature "shared by nearly all modern MDIs." Anderson Opening Rep. ¶ 52. I explain my disagreement more fully in Section V, below,

but suffice it to say that the identification of a handful of prior art references, including the '066 Patent, that allegedly disclose the incorporation of a dose counter or dose indicator into an MDI does not suggest that such features were ubiquitous, and it incorrectly conflates dose indicators with dose counters, the former of which were more common. To the contrary, the availability of prior art references allegedly teaching the use of dose counters or indicators in MDIs as of the priority date, in combination with the dearth of marketed MDIs containing such dose counters as of the priority date, amply demonstrates the difficulty in designing such devices. I addressed such considerations in more detail in my Opening Report in connection with objective indicia of non-obviousness. *See, e.g.,* Lewis Opening Reps. §§ IX.A.1-2, B, *infra* Section V.

102. I also disagree with Mr. Anderson's reliance on the '066 Patent in service of an alleged distinction between "tape-based dose counters" and "gear-based dose counters." *See* Anderson Opening Rep. ¶¶ 53-54. In my opinion, this distinction is not meaningful and the POSA would not have viewed mechanical dose counters and dose indicators as falling into two distinct camps. Rather, the POSA would have understood that mechanical dose counters, like other mechanical devices, used a variety of mechanisms to display information and that those mechanisms could be adapted for use in a variety of different inhalation products.

J. The '627 Patent

103. U.S. Patent No. 6,446,627 (the "'627 Patent") is entitled "Inhaler Dose Counter" and lists Nicholas John Bowman, Michael John Holroyd, Costaninos Panayi, and William Richard Treneman as inventors. The '627 Patent further lists Norton Healthcare Limited as the assignee.

104. Mr. Anderson relies on the '627 Patent for the following propositions: (1) "the metered dose inhaler (MDI) is the gold standard for delivery of medication to the lungs and is the most commonly used device in the treatment of asthma," Anderson Opening Rep. ¶ 47; (2) "[t]he canister generally includes a valve with a valve stem that compresses, allowing medication to be

discharged,” Anderson Opening Rep. ¶ 49; (3) “[t]he MDI actuator typically includes a location or structure adapted to receive the valve stem (‘valve stem block’),” Anderson Opening Rep. ¶ 49; (4) “movement of the valve stem into the discharge position is caused by pushing down on the canister, causing the valve stem to compress in the valve block,” Anderson Opening Rep. ¶ 49; (5) “[w]hen the valve stem moves a defined distance to the discharge position, a dose of medication is dispensed,” Anderson Opening Rep. ¶ 49; (6) “[i]n tape-based dose counters, the count is displayed on a tape, which is typically wrapped around a first axis, then, as the inhaler is actuated, a second axis rotates, drawing the tape display to the second axis (or take up spool),” Anderson Opening Rep. ¶ 54; (7) “[t]he surface of the tape is covered with a form of indicia, such as numbers, which provides information about the number of doses remaining in the inhaler, and is visible through a display located on the body of the inhaler when the tape is drawn from the first axis to the take up spool,” Anderson Opening Rep. ¶ 54; and (8) “many of the tape-based systems record a count when a pin is depressed by the canister,” Anderson Opening Rep. ¶ 55.

105. Even if one were to assume that the ’627 Patent supports these propositions, the ’627 Patent does not disclose the inventions of the Asserted Claims. For example, despite discussing features of a canister housing (referred to in the ’627 Patent as an “actuator body”), the ’627 Patent does not disclose a canister housing containing “inner wall canister support formations,” let alone the location of any “inner wall canister support formation” relative to the actuation member of a dose counter. To the contrary, the ’627 Patent’s disclosure of a dose counter and a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features

of the dose counter could improve counter accuracy. The '627 Patent also fails to disclose additional aspects of the Asserted Claims, including but not limited to the precise location of the dose counter relative to a datum plane passing through a shoulder of the valve stem block, or a regulator, as recited in the Asserted Claims.

K. The '668 Patent

106. U.S. Patent No. 8,584,668 (the "'668 Patent") is entitled "Inhalation Device" and lists Darren Hodson and Jorgen Rasmussen as inventors.

107. Mr. Anderson relies on the '668 Patent in support of his argument that "ribs" were "essentially ubiquitously used in MDIs." Anderson Opening Rep. ¶¶ 169-170, 176. As I explain below, I disagree that ribs (or any variation of "inner wall canister support formations") were ubiquitous in inhalers as of 2008, nor are they ubiquitous today. *See infra* Section V.

108. I also do not agree that Mr. Anderson has identified the presence of "inner wall canister support formations" in the '668 Patent. In support, he merely circles two unlabeled features in Figure 9 of the '668 Patent. *See, e.g.*, Anderson Opening Rep. ¶ 176. I reproduce Mr. Anderson's annotated image below.

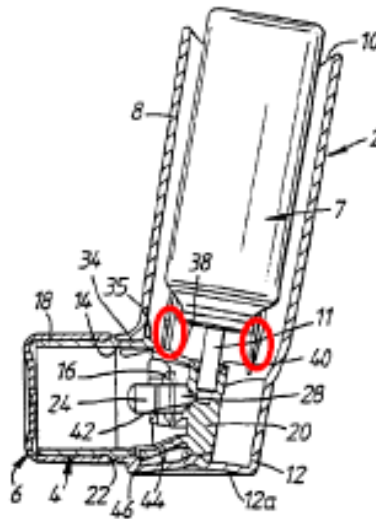


Fig.9

'668 Patent

(2006)

It is not clear what the structure or purpose is of the features Mr. Anderson has circled in Figure 9, and it is certainly not clear that the circled features are “inner wall canister support formations.” Indeed, it is not clear from Figure 9 whether the circled features extend behind the canister. Mr. Anderson has not pointed to any text in the '668 Patent explaining that what he has circled in Figure 9, nor am I able to identify any text associated with this figure other than the statement that “Fig. 9 illustrates a vertical sectional view (along section B-B) of the inhaler of Fig. 1.” '668 Patent, 4:9-10. This description does not provide any clarity as to the identity of the features Mr. Anderson has circled. Certainly, it does not suggest “[t]he importance of inclusion of ribs” Anderson Opening Rep. ¶¶ 170, 248, nor that the POSA “would have been motivated to select or modify ribs to include tapered or stepped designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve, and to improve tolerance control, fit, and function.” Anderson Opening Rep. ¶¶ 176, 254.

109. Even if one were to assume that the circled features are support ribs and thus are “inner wall canister support formations” within the meaning of the ’289 and ’587 Patents (and as I explain above, there is no basis to do so), the ’668 Patent does not describe (in Figure 9 or anywhere else) the location of the support formations relative to the actuation member of a dose counter or even a dose indicator. To the contrary, the ’668 Patent’s disclosure of a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in MDI inhalers.

L. The ’260 Publication

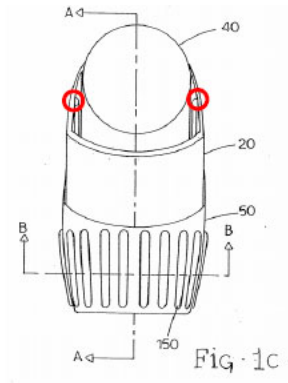
110. International Publication No. WO2004/060260 (the “’260 Publication”) is entitled “Drug Delivery System with Vented Mouthpiece” and names Michael L. King as the inventor.

111. The focus of the ’260 Publication is on a “vented mouthpiece” that “provide[s] an air flow channel . . . to facilitate intake” of a medication. ’260 Publication, Abstract. The ’260 Publication recognizes that ordinarily, airflow for medication intake in an MDI comes through the device itself. ’260 Publication, 1:30-2:7. However, the ’260 Publication recognizes that there may be instances in which there is a reason to restrict airflow through the device, for instance, to enclose internal inhaler components. ’260 Publication, 1:30-2:7. The mouthpiece of the ’260 Publication is designed to facilitate airflow under such circumstances. ’260 Publication, 1:30-2:7.

112. The ’260 Publication would have confirmed the POSA’s understanding that “[a]irflow through an inhalation device may have the potential to influence the plume and thus the deposition profile of the dose of medicament. Airflow in the dose delivery passage of an inhaler, intentionally or unintentionally typically interacts with the plume during dose delivery.” ’260 Publication, 2:22-25. Accordingly, the POSA would have understood that alterations to a canister housing would have the potential to alter airflow and thus alter plume/medication deposition profile—which in turn would could bear on the efficacy of the medication being administered.

Thus, the disclosure of the '260 Publication would have reinforced for the POSA the desire to avoid altering the interior of the canister housing when possible.

113. In his Opening Report, Mr. Anderson asserts that two features shown in Figure 1c of the '260 Publication are “inner wall canister support formations.” I have reproduced Mr. Anderson’s annotated version of Figure 1c from paragraph 176 of his Opening Report below.



'260 Publication

(2004)

Mr. Anderson relies on these features in support of his argument that “ribs” were “essentially ubiquitously used in MDIs.” Anderson Opening Rep. ¶¶ 169-170, 176. As I explain below, I disagree that ribs (or any variation of “inner wall canister support formations”) were ubiquitous in inhalers as of the priority date, nor are they ubiquitous today. *See infra* Section V.

114. I also do not agree that Mr. Anderson has identified the presence of “inner wall canister support formations” in the '260 Publication. It is not clear what the structure or purpose is of the features Mr. Anderson has circled in Figure 1c, and it is certainly not clear that the circled features are “inner wall canister support formations.” Mr. Anderson has not pointed to any text in the '260 Publication explaining that what he has circled in Figure 1c, nor am I able to identify any text associated with this figure other than the statement that “FIGS. 1A through 1D respectively illustrate perspective, side cross-sectional, top, and frontal views of an oral inhaler according to

the present invention.” ’260 Publication, 3:32-33. This description does not provide any clarity as to the identity of the features Mr. Anderson has circled. Certainly, it does not suggest “[t]he importance of inclusion of ribs” Anderson Opening Rep. ¶¶ 170, 248, nor that the POSA “would have been motivated to select or modify ribs to include tapered or stepped designs to aid in the insertion and removal of the canister, so as to avoid angled insertion, which may cause unwanted gassing of the valve, and to improve tolerance control, fit, and function.” Anderson Opening Rep. ¶¶ 176, 254.

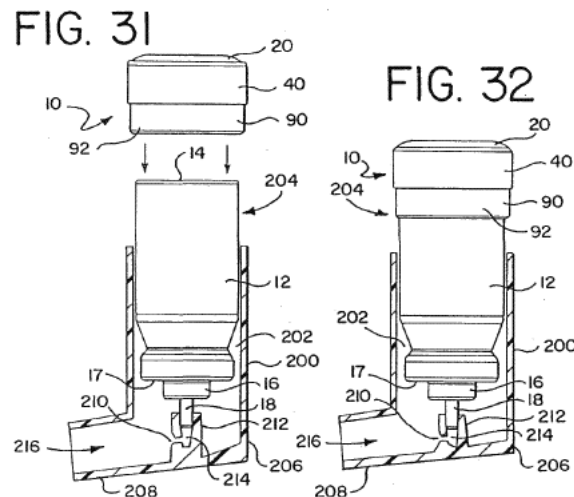
115. Even if one were to assume that the circled features are support ribs and thus are “inner wall canister support formations” within the meaning of the ’289 and ’587 Patents (and as I explain above, there is no basis to do so), the ’220 Publication does not disclose a dose counter or indicator, and so does not describe (in Figure 1c or anywhere else) the location of the support formations relative to the actuation member of a dose counter or dose indicator. To the contrary, the ’220 Patent’s failure to mention any inner wall canister support formations is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in MDI inhalers. Certainly, the ’260 Publication—the text of which is completely silent regarding inner wall canister support formations—would not have provided the POSA with a reason to include inner wall canister support formations in a canister housing for use with a dose counter, let alone suggested that any particular location of an inner wall canister support formation relative to a dose counter component would be advantageous.

M. The ’191 Publication

116. U.S. Patent Application Publication No. 2005/0087191 (the “’191 Publication”) is entitled “Indicating Device with Warning Dosage Indicator” and lists Robert Morton and Winston Z. Lu as inventors. The ’191 Publication was before the examiner during prosecution of each of the Asserted Patents.

117. Mr. Anderson relies on the '191 Publication to describe what he describes as “common structural traits” of metered dose inhalers, which, according to him, include dose counters. *See* Anderson Opening Rep. ¶¶ 47, 48, 49, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B, *infra* Section V.

118. I note that Mr. Anderson does not rely on the '191 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. Indeed, the '191 Publication teaches configurations of dose counters that differ from those claimed substantially—including because the first embodiment described by the '191 Publication involves a dose counter affixed to the flat portion of the canister. I have provided an exemplary figure showing such a dose counter from the '191 Publication below:



119. In my opinion, the POSA would have had reason to pursue a dose counter in this configuration rather than the dose counters of the claimed invention, for all the reasons I explain below in Section V and in response to Mr. Anderson’s various obviousness theories.

120. In addition, the '191 Publication recognizes the need to avoid disrupting inhaler airflow with bulky dose counter components. In an embodiment of the '191 Publication that is not mounted on the flat portion of the medication canister, the '191 Publication emphasizes the “relatively small diameter” of certain features, which permit it to be “easily mounted within small spaces within the housing . . . such that the assembly does not interfere with the dispensing of the medicament from the orifice or with the airflow generated by the patient in administering the medicament.” '191 Publication, ¶¶ [0275], [0285]. The '191 Publication would have confirmed for the POSA the relative difficulty in developing a dose counter situated partially below the canister, as compared with one situated on top of the canister housing, since the former is subject to greater restrictions on size and raises concerns regarding airflow changes. Accordingly, the POSA evaluating the '191 Publication would have read it to teach away from the claimed invention and toward the use of “top-mounted” dose counting devices.

121. In addition, I note that for example Figures 31 and 32 of the '191 Publication, show a dose counter affixed to the flat portion of the medication canister, depict a canister housing without any inner wall canister support formations. '191 Publication, Figure 31, 32. Indeed, Mr. Anderson does not identify any disclosure of inner wall canister support formations in the '191 Publication. This is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in MDI inhalers, nor would the POSA have appreciated as of the priority date that particular configurations of inner wall canister support formations could have advantages for counting accuracy and robustness.

122. During prosecution of each of the Asserted Patents, the examiner considered the '191 Publication, but declined to find that it rendered unpatentable the Asserted Claims. *See, e.g.,* '289 Patent, U.S. Patent Documents; '587 Patent, U.S. Patent Documents; '156 Patent, U.S.

Patent Documents; '808 Patent, U.S. Patent Documents. I have conducted an independent analysis of the '191 Publication, and in my opinion, the '191 Publication does not render invalid the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the '191 Publication does not render invalid those claims.

N. The '712 Publication

123. WO 2007/103712 (the "'712 Publication") is entitled Method and Apparatus for Metered Dose Dispensing" and lists Richard D. Brewer, Peter D. Hodson, Graham Purkins, and David J. Steven as inventors. 3M Innovative Properties Company is listed as the Applicant.

124. Mr. Anderson relies on the '712 Publication to disclose what he describes as "common structural traits" of metered dose inhalers, which, according to him, include dose counters. *See* Anderson Opening Rep. ¶¶ 47, 48, 49, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B; *infra* Section V.

125. I note that Mr. Anderson does not rely on the '712 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. To the contrary, the '712 Publication teaches away from the claimed invention—it teaches the mounting of dose counting/indicating devices on either end of the canister housing, rather than partially within the housing for operation by the medicament canister. *See, e.g.,* '712 Publication, 3:6-24, 18:17-30. The '721 Publication notes the complicated interrelationship between canister and actuator that is critical to the success of MDIs, '712 Publication, 1:29-33, and goes on to explain that "a common problem with other actuator mounted (internal) dose

counters” is that they “interfere with the emerging medicament spray,” ’712 Publication, 18:28-30.

126. I also disagree with Mr. Anderson’s reliance on the ’712 Publication in service of an alleged distinction between “tape-based dose counters” and “gear-based dose counters.” *See* Anderson Opening Rep. ¶¶ 53-54. In my opinion, this distinction is not meaningful and the POSA would not have viewed mechanical dose counters and dose indicators as falling into these two distinct camps. Rather, the POSA would have understood that mechanical dose counters, like other mechanical devices, used a variety of mechanisms to display information and that those mechanisms could be adapted for use in a variety of different inhalation products.

O. The ’139 Publication

127. EP 1 369 139 A1 (the “’139 Publication”) is entitled “Dose Indicators and Dispensing Canister-Indicator Assemblies” and lists Eduard Marx as an inventor. 3M Innovative Properties Company is listed as the Applicant.

128. Mr. Anderson relies on the ’139 Publication to disclose what he describes as “common structural traits” of metered dose inhalers, which, according to him, include dose counters. *See* Anderson Opening Rep. ¶¶ 47, 48, 49, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B; *infra* Section V. In the case of the ’139 Publication, its primary embodiment is a dose indicator, not a dose counter. *See, e.g.* ’139 Publication, Fig. 5.

129. I note that Mr. Anderson does not rely on the ’139 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or

obvious. To the contrary, the '139 Publication teaches away from the claimed invention—it teaches the mounting of dose counting/indicating devices onto the canister, rather than devices that are moveable relative to the canister with actuation members that are part of the dose counter and that extend into the canister housing, *see, e.g.*, '139 Publication, ¶¶ [0021], [0022], [0026], [0067], [0076], and it reinforces that other dose counter configurations—such as ones that are not confined to the diameter of the medication canister—could interfere with airflow or require alterations to the shape of the canister housing. *See, e.g.*, '139 Publication, ¶¶ [0007], [0012], [0023].

130. I also disagree with Mr. Anderson's reliance on the '139 Patent in service of an alleged distinction between “tape-based dose counters” and “gear-based dose counters.” See Anderson Opening Rep. ¶¶ 53-54. In my opinion, this distinction is not meaningful and the POSA would not have viewed mechanical dose counters and dose indicators as falling into these two distinct camps. Rather, the POSA would have understood that mechanical dose counters, like other mechanical devices, used a variety of mechanisms to display information and that those mechanisms could be adapted for use in a variety of different inhalation products.

P. GB '489

131. U.K. Patent Application GB 2,320,489 (“GB '489”) is entitled “Inhaler dose counter” and lists Nicholas John Bowman, Constantinos Panayi, William Richard Treneman, and Michael John Holroyd as inventors. GB '489 further lists Norton Healthcare Limited as an applicant. GB '489 was before the examiner during prosecution of each of the Asserted Patents.

132. Mr. Anderson relies on GB '489 for the following propositions: (1) “the metered dose inhaler (MDI) is the gold standard for delivery of medication to the lungs and is the most commonly used device in the treatment of asthma,” Anderson Opening Rep. ¶ 47; (2) “[t]he canister generally includes a valve with a valve stem that compresses, allowing medication to be discharged,” Anderson Opening Rep. ¶ 49; (3) “[s]ince [2003], most MDIs have included

integrated dose counters,” Anderson Opening Rep. ¶ 52; and (4) “[i]n tape-based dose counters, the count is displayed on a tape, which is typically wrapped around a first axis, then, as the inhaler is actuated, a second axis rotates, drawing the tape display to the second axis (or take up spool),” Anderson Opening Rep. ¶ 54.

133. Even if one were to assume that GB ’489 supports these propositions, GB ’489 does not disclose the inventions of the Asserted Claims. For example, despite discussing features of a canister housing (referred to in GB ’489 as an “actuator body”), GB ’489 does not disclose a canister housing containing “inner wall canister support formations,” let alone the location of any “inner wall canister support formation” relative to the actuation member of a dose counter. To the contrary, GB ’489’s disclosure of a dose counter and a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy. GB ’489 also fails to disclose additional aspects of the Asserted Claims, including but not limited to the precise location of the dose counter relative to a datum plane passing through a shoulder of the valve stem block, or a regulator, as recited in the Asserted Claims. .

134. During prosecution of each of the Asserted Patents, the examiner considered GB ’489, but declined to find that it rendered unpatentable the Asserted Claims. *See, e.g.*, ’289 Patent, Foreign Patent Documents; ’587 Patent, Foreign Patent Documents; ’156 Patent, Foreign Patent Documents; ’808 Patent, Foreign Patent Documents. I have conducted an independent analysis of GB ’489, and in my opinion, GB ’489 does not render invalid the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence

that GB '489 does not render invalid those claims.

Q. The '558 Publication

135. U.S. Patent Application Publication No. 2005/0209558 (the "'558 Publication") is entitled "Dose Indicators and Dispensing Canister-Indicator Assemblies" and lists Eduard Marx as an inventor. 3M Innovative Properties Company is listed as the Applicant.

136. Mr. Anderson relies on the '558 Publication to disclose what he describes as "common structural traits" of metered dose inhalers, which, according to him, include dose counters. See Anderson Opening Rep. ¶¶ 47, 48, 49, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. See Lewis Opening Reps. §§ IX.A.1-2, B; *infra* Section V. In the case of the '558 Publication, its primary embodiment is a dose indicator, not a dose counter. See, e.g. '558 Publication, Fig. 5.

137. I note that Mr. Anderson does not rely on the '558 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. To the contrary, the '558 Publication teaches away from the claimed invention—it teaches the mounting of dose counting/indicating devices onto the canister, rather than devices that are moveable relative to the canister with actuation members that are part of the dose counter and that extend into the canister housing, and it reinforces that other dose counter configurations—such as ones that are not confined to the diameter of the medication canister—could interfere with airflow or require alterations to the shape of the canister housing. See, e.g., '558 Publication, ¶¶ [0007], [0025], [0027], [0027], [0030], [0044], [0088], [0096].

138. I also disagree with Mr. Anderson's reliance on the '558 Patent in service of an

alleged distinction between “tape-based dose counters” and “gear-based dose counters.” See Anderson Opening Rep. ¶¶ 53-54. In my opinion, this distinction is not meaningful and the POSA would not have viewed mechanical dose counters and dose indicators as falling into these two distinct camps. Rather, the POSA would have understood that mechanical dose counters, like other mechanical devices, used a variety of mechanisms to display information and that those mechanisms could be adapted for use in a variety of different inhalation products.

R. The '755 Patent

139. United Kingdom Patent No. GB 994,755 (the “’755 Patent”) is entitled “Aerosol Dispensing Apparatus.”

140. Mr. Anderson relies on the ’755 Patent to disclose what he describes as “common structural traits” of metered dose inhalers, which, according to him, include dose counters. See Anderson Opening Rep. ¶¶ 47, 48, 49, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. See Lewis Opening Reps. §§ IX.A.1-2, B; *infra* Section V. In the case of the ’755 Patent, I disagree that it discloses any dose counting or indicating device whatsoever. Mr. Anderson cites the ’755 Patent without specifying any particular page or line—regardless, I disagree that any page or line or figure in the ’755 Patent discloses a dose counter or dose indicator.

141. Mr. Anderson also relies on the ’755 Patent to suggest that “a series of ‘ribs’” in the canister housing “has been common in MDI inhalers for decades.” Anderson Opening Rep. ¶ 50. I do not agree that the ’755 Patent supports this contention. The ’755 Patent simply provides one example—and arguably the first example—of a canister housing that contains ribs. See, e.g. Lewis 2007, at 236, CIPLA-BDI_0184749. The ’755 Patent does not suggest (alone or in

combination with the other references Mr. Anderson has selected to demonstrate the presence of ribs) that all or even most MDIs have included ribs for decades. As I explain in more detail where relevant to Mr. Anderson's obviousness theories, I disagree that support rails were "essentially ubiquitous" as of the priority date. *See infra* Section V. The prior art and the body of marketed inhalers (both as of the priority date and today) are replete with examples of inhalers that do not contain support rails. *See, e.g.,* Lewis Opening Reps. §§ IX.A.1-2, B; *infra* Section V.

142. I note that Mr. Anderson does not rely on the '755 Patent as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. Nor could he do so, since the '755 Patent does not disclose a dose counter, as every one of the asserted claims requires.

S. The '159 Publication

143. European Patent Application No. 1 321 159 A1 (the "'159 Publication") is entitled "Pressurized Metered Dose Inhaler (pMDI) Actuators With Laser Drilled Orifices" and lists Rebecca Jayne Davies as an inventor. Chiesi Farmaceutici S.p.A. is listed as the Applicant.

144. The '159 Publication explains that "[t]he shape and direction of the discharge plume and the dispersion of the droplets or particles therein are critical to effective administration of a controlled dose to the patient." '159 Publication, ¶ [0015]. This statement, and the '159 Publication's effort to optimize canister housing features to control the discharge plume would have reinforced for the POSA the importance of actuator features in effective dose delivery. In particular, the POSA would have been wary of making alterations to existing actuators given the concern that such changes could result in alteration in effective administration of the drug to the patient.

145. Mr. Anderson relies on the '159 Publication's Figure 3 to suggest that "a series of 'ribs'" in the canister housing "has been common in MDI inhalers for decades." Anderson

Opening Rep. ¶ 50. I do not agree that the '159 Publication supports this contention. The '159 Publication simply provides one example of a canister housing that contains ribs. The '159 Publication does not suggest (alone or in combination with the other references Mr. Anderson has selected to demonstrate the presence of ribs) that all or even most MDIs have included ribs for decades. As I explain in more detail where relevant to Mr. Anderson's obviousness theories, I disagree that support rails were "essentially ubiquitous" as of the priority date. *See infra* Section V. The prior art and the body of marketed inhalers (both as of the priority date and today) are replete with examples of inhalers that do not contain support rails. *See, e.g.,* Lewis Opening Reps. §§ IX.A.1-2, B, *infra* Section V.

146. The '159 Publication does not feature inner wall canister support formations as a core element of its disclosure. Rather, the '159 Publication is primarily directed to actuators (i.e., inhaler bodies) with laser drilled orifices. *See, e.g.,* '159 Publication, ¶ [0001]. The '159 Publication states only that a canister can be inserted into an actuator "and located by means of ribs 11." '159 Publication, ¶ [0012]. This disclosure would not have provided the POSA a reason to include ribs in a canister housing designed to contain a dose counter, and certainly would not have suggested to the POSA that such ribs would be useful in preventing rocking of the canister that could adversely impact counter accuracy and robustness.

147. I note that Mr. Anderson does not rely on the '159 Patent as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. Nor could he do so, since the '159 Patent does not disclose a dose counter, as every one of the Asserted Claims requires.

T. The '965 Publication

148. International Publication No. WO 2006/126965 (the "'965 Publication") is entitled "Dose Counter Device for Inhaler" and lists Lennart Brunnberg, Stephan Olson, and Anders

Wieselblad as inventors.

149. Mr. Anderson relies on the '965 Publication to describe what he describes as “common structural traits” of metered dose inhalers, which, according to him, include dose counters. *See* Anderson Opening Rep. ¶¶ 48, 49, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. ¶¶ IX.A.1-2, B.

150. I note that Mr. Anderson does not rely on the '965 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. And indeed, the '965 Publication teaches away from many of those limitations. For example, the '965 Publication states that certain prior art dose counters relied on the displacement of the medicament canister to determine whether the medicament canister had delivered a dose. However, the '965 Publication states that such displacement-driven dose counters suffered from dose counting errors because of “manufacturing variations” in the medicament canisters or dose counters and the need to control for spring force and other complex mechanisms. *See* '965 Publication, 1:11-2:31. Thus, the '965 Publication describes dose counters mounted on the “distal end of the inhaler” (i.e., on top of the inhaler from the perspective of the patient using the device). *See* '965 Publication, 3:1-24, Figs. 1-20, Claim 1.

151. Additionally, consistent with the prior art as a whole, the '965 Publication emphasizes the dangers of undercounting relative to overcounting. Thus, the '965 Publication states: “[F]rom the users’ point of view, it is better to have at hand a dose counter device that occasionally may register a dose delivery even though no dose was in fact delivered, than to have

it the other way around. In this way, the user can not unintentionally run out of medicament.”
'965 Publication, 2:9-19.

152. Notably, the '965 Publication does not disclose any embodiments comprising a canister housing that has inner wall canister support formations (such as support rails) and a dose counter. The '965 Publication's disclosure of a dose counter and a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy. The '965 Publication also fails to disclose additional aspects of the Asserted Claims, including but not limited to the precise location of the dose counter relative to a datum plane passing through a shoulder of the valve stem block, or a regulator, as recited in the Asserted Claims.

U. The '817 Publication

153. U.S. Patent Application Publication No. 2007/0277817 (the "'817 Publication") is entitled "Pressurized Metered Dose Inhaler System" and lists Kevin Innocenzi as the inventor.

154. Mr. Anderson relies on the '817 Publication to describe what he describes as "common structural traits" of metered dose inhalers, which, according to him, include dose counters. *See* Anderson Opening Rep. ¶¶ 48, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B; *see also infra* Section V.

155. I note that Mr. Anderson does not rely on the '817 Publication as a basis for

asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. And indeed, the '817 Publication teaches away from many of those limitations. For example, the '817 Publication discloses a dose counter that “is mounted in such a way that it does not interfere with actuating the metered dose valve assembly,” '817 Publication, ¶ [0025], Figs. 2-4, and depicts an actuator pawl that is located well above the valve stem block, '817 Publication, Figs. 2-4.

156. Notably, the '817 Publication does not disclose any embodiments comprising a canister housing that has inner wall canister support formations (such as support rails) and a dose counter. The '817 Publication's disclosure of a dose counter and a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy. The '817 Publication also fails to disclose additional aspects of the Asserted Claims, including but not limited to the precise location of the dose counter relative to a datum plane passing through a shoulder of a the valve stem block, or a regulator, as recited in the Asserted Claims .

V. The '044 Publication

157. International Publication No. WO 2005/113044 (the “044 Publication”) is entitled “Dispensing Apparatus With Dosage Counter” and lists Simon Ingram, Nick Campling, and Duncan Bradley as inventors/applicants. The '044 Publication further lists Bepak PLC as an applicant.

158. Mr. Anderson relies on the '044 Publication for the following propositions:
(1) “[m]odern MDIs are typically comprised of an aerosol canister, containing medication

formulated with a propellant and an actuator with a mouthpiece, typically a plastic housing that receives the canister,” Anderson Opening Rep. ¶ 48; and (2) “[s]ince [2003], most MDIs have included integrated dose counters,” Anderson Opening Rep. ¶ 52. I disagree with Mr. Anderson that dose counters were typical components of an MDI as of the priority date. As I explain in my Opening Reports, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B; *see also infra* § V.

159. I note that Mr. Anderson does not rely on the ’044 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. And indeed, the ’044 Publication teaches away from many of those limitations. For example, the ’044 Publication notes disadvantages with certain dose indicators before its publication that highlight the complexity of dose indicator (and dose counter). In particular, the ’044 Publication explains that one device “suffered from reliability of operation of the medication dispenser and the pawls, for example. If the pawls are too stiff relative to the internal spring bias then the medication dispenser may dispense a dose before the pawls flex sufficiently to rotate the indicator wheel; a dose would be delivered without the counter registering it. Alternatively, if the pawls are too flexible relative to the internal spring bias then the pawls may flex sufficiently to rotate the indicator wheel before the medication dispenser has dispensed a dose; a dose would be registered by the counter but not actually delivered. ’044 Publication, at 1:21-2:10. This disclosure would have reinforced to the POSA the difficulties in designing a robust and accurate counter, and taught away from the pawl-based system of the Asserted Claims. In an effort to avoid that disadvantage, the ’044 Publication teaches an annular counting mechanism that is “preferably . . .

located *around* the container.” ’044 Publication, 6:23-7:2 (emphasis added). And as is clear from Figures 2, 3, and 9 of the ’044 Publication, the dose counter of the ’044 Publication is located well above the valve stem block.

160. Notably, the ’044 Publication does not disclose any embodiments comprising a canister housing that has inner wall canister support formations (such as support rails) and a dose counter. The ’044 Publication’s disclosure of a dose counter and an canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy. The ’044 Publication also fails to disclose additional aspects of the Asserted Claims, including but not limited to a regulator as recited in the Asserted Claims.

W. Lewis

161. “Metered-Dose Inhalers: Actuators Old and New” (“Lewis”) is an article I wrote that was published in the journal *Expert Opinions on Drug Delivery* in 2007.

162. As the title of the article reflects, my intent was to convey the importance of actuator design on the function of metered dose inhalers. Mr. Anderson focuses exclusively on my statements regarding “support ribs” in inhaler bodies (which I refer to throughout my article as “actuators”). Anderson Opening Rep. ¶¶ 51, 169, 177-78, 247, 249, 255-56. Those statements read in full:

Initially, the actuator's housing extended only to the top of the valve ferrule; the redesign of the actuator to encompass and support the canister did not occur until 1965 [101]. This modification introduced four equally spaced ribs to locate the container, and provided an annular passageway to draw air using the mouthpiece. The additional support provided by the modified actuator was introduced to prevent accidental opening of the valve as a result of unintentional

axial movement of the valve stem. The updated design remains an important feature of present actuators.

Lewis at 236.

163. I do not agree with Mr. Anderson’s interpretation of my article—the POSA would not have understood this statement to mean that support rails were “essentially ubiquitous” as of the priority date, because the POSA’s knowledge of prior art devices would have belied that fact. *Contra* Anderson Opening Rep. ¶¶ 169. As I explain below, the prior art and the body of marketed inhalers (both as of the priority date and today) are replete with far more than six examples of inhalers that do not contain support rails. *Infra* Section V.

164. In addition, I take issue with Mr. Anderson’s alteration of what I wrote in, for example, paragraph 169 of his Opening Report. In particular, he added the bracketed language to the penultimate sentence of the paragraph I excerpted above, stating that “the “support provided by the modified actuator [and ribs] was introduced to prevent accidental opening of the valve as a result of unintentional axial movement of the valve stem.” As the preceding sentence makes clear, I stated that ribs were introduced “to locate the container, and provided an annular passageway to draw air using the mouthpiece.” Lewis 2007, at 236. As the POSA would have understood, the reference to “the additional support” in the following sentence refers to the support other than the ribs—i.e., support provided by extension of the actuator beyond the ferrule. This is made plain by my reliance on the ’755 Patent, which states that “it is an important feature of this invention that the applicator be constructed with a cylindrical barrel or housing portion which encloses substantially the entire length of the pressurized container thereby supporting the container in the proper position with no possibility of lateral movement of the valve stem.” ’755 Patent, 2:55-60. In contrast, the ’755 Publication reports that “inwardly extending ribs . . . support the container . . . within the barrel and space it from the inner surface of the barrel to provide a clearance . . . which

permits the passage of air around the container to scavenge the medicament-containing aerosol from the delivery tub . . . into the oral cavity of the user.” ’755 Patent, 45-54.

165. Regardless, the POSA would certainly not have understood my article to suggest that ribs were useful to avoid canister rocking in connection with dose counters. As is plain, I refer in my article to dose counters but do not in any way connect them with the presence or location of ribs, nor do I suggest that ribs should be located in any particular configuration relative to any component of a dose counter. In fact, my article expresses substantial skepticism of the utility of dose counters—I state that “[t]hese developments represent significant modifications to the MDI actuator as a patient interface, and clearly require careful analysis of the patient benefits and justification of the additional final unit cost.” Lewis 2007, at 241, CIPLA-BDI_0184754. In that sense, my article teaches away from the claimed invention, because I suggested that dose counters could alter the familiar way in which patients experience their device, and because they could increase the cost of MDIs more than is justified by their benefits. Indeed, in Figure 1 of my article—the only time I depict an MDI actuator in the article—I do not identify any ribs or dose counters. Lewis 2007, at 236.

166. Furthermore, I note that the only mechanical (rather than electronic) dose counter I was able to point to in my 2007 article was that contained in Seretide. Seretide utilizes a system similar to that of the ’514 Publication in that it affixes its dose counter to the medication canister, and the canister-counter assembly moves together to interact with a pin that is part of the canister housing. As I describe in detail above with respect to the ’514 Publication, and below with respect to Mr. Anderson’s anticipation and obviousness theories, that approach differs fundamentally from the one claimed in the Asserted Patents.

The remainder of my article addresses additional components of the canister housing and

notes the impact they can have on inhaler performance. This is clear from the abstract itself, which explains that “This review focuses upon developments since the actuator’s introduction as an integral part of the metered-dose inhaler and discusses key aspects of its design that influence lung deposition potential. The ability of the actuator to reduce unwanted oropharyngeal drug deposition, facilitate correct patient use and provide valuable patient feedback is highlighted.” In other words, the actuator can be critical to the success of an MDI, and the POSA would have had reason to avoid altering a successful actuator for fear of altering the efficacy of the device as a whole. For example, I explain that “when MDIs are used incorrectly, patients are likely to receive a reduced or even a non-existent dose to the lungs” and emphasize the importance as the “actuator’s role as the patient interface.” Lewis 2007, at 236, CIPLA-BDI_0184749. This would have given the POSA reason to avoid altering a familiar MDI actuator or interface, including by altering the resistance that is required to actuate the inhaler, or simply introducing features that require changes to actuator geometry that could affect the feel of breathing through the inhaler or affect the risk of actuator blockage. Lewis 2007, at 236-37, CIPLA-BDI_0184749-750. The POSA would have been concerned that such changes could alter device performance, or at a minimum, require expensive and time-consuming testing to ensure they do not. Indeed, I reflect in my article on “the ever increasing amount of data required to gain marketing approval,” and note the “capital investment risks” and “increas[e in] the likelihood of undesirable delays and costs of product development and approval” that changes in actuators can entail. Lewis 2007, at 242, CIPLA-BDI_0184755. I also note that such changes must be highly cost effective to be successful. Lewis 2007, at 242, CIPLA-BDI_0184749. All of these concerns would have given the POSA reason to avoid making changes to the actuator of an MDI.

X. The ’949 Publication

167. U.S. Patent Application Publication No. WO 2006/0107949 (the “’949

Publication”) is entitled “Holder for a Dispensing Container System” and lists Michael Birsha Davies, James William Godfrey, and Pal Kenneth Rand as inventors. The ’949 Publication was before the examiner during prosecution of each of the Asserted Patents.

168. Mr. Anderson relies on the ’949 Publication to describe what he describes as “common structural traits” of metered dose inhalers, which, according to him, include dose counters and ribs. *See* Anderson Opening Rep. ¶¶ 48, 49, 51, 52. I disagree. As I explain in my opening report, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. ¶¶ IX.A.1-2, B.

169. The discussion of “ribs 41a-c” in paragraphs [0075] and [0076], as depicted in Figures 6 and 7, are not “inner wall canister support formations” in that they do not extend inwardly from the canister housing towards the medication canister, but rather fit in between two components of the complicated housing shown in Figure 6. These features also do not extend longitudinally along the inner wall of the canister housing, but are rather perpendicular to the direction of canister movement.

170. During prosecution of each of the Asserted Patents, the examiner considered the ’949 Publication, but declined to find that it rendered unpatentable the Asserted Claims. *See, e.g.,* ’289 Patent, U.S. Patent Documents; ’587 Patent, U.S. Patent Documents; ’156 Patent, U.S. Patent Documents; ’808 Patent, U.S. Patent Documents. I have conducted an independent analysis of the ’949 Publication, and in my opinion, the ’949 Publication does not render invalid the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the ’949 Publication does not render invalid those

claims.

Y. The '518 Publication

171. U.S. Patent Application Publication No. 2007/0062518 (the "'518 Publication") is entitled "Atomizer" and lists Johannes Geser, Burkhard P. Metzger, Christian Goldberg, Michael Schyra, Ralf Thommes, Birgit Westmeier, Guido Schmiedel, Hubert Kunze, and Georg Boeck as inventors.

172. Mr. Anderson relies on the '518 Publication for the proposition that, "[s]ince [2003], most MDIs have included integrated dose counters." Anderson Opening Rep. ¶ 52. I disagree with Mr. Anderson that dose counters were typical components of an MDI as of the priority date. As I explain in my Opening Reports, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B; *see also infra* Section V. Despite that, I note that Mr. Anderson does not rely on the '518 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious.

173. Notably, the '518 Publication does not disclose any embodiments comprising a canister housing that has inner wall canister support formations (such as support rails) and a dose counter. The '518 Publication's disclosure of a dose counter and a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy. The '518 Publication also fails to disclose additional aspects of the

Asserted Claims, including but not limited to the precise location of the dose counter relative to a datum plane passing through a shoulder of the valve stem block, or a regulator, as recited in the Asserted Claims.

Z. The '102 Publication

174. U.S. Patent Application Publication No. 2007/0210102 (the "'102 Publication") is entitled "Indicator For a Device For Dispensing A Liquid or Powdery Product" and lists Giuseppe Stradella and Fabio Stradella as inventors.

175. Mr. Anderson relies on the '102 Publication for the proposition that, "[s]ince [2003], most MDIs have included integrated dose counters." Anderson Opening Rep. ¶ 52. Anderson Opening Rep. ¶ 52. I disagree with Mr. Anderson that dose counters were typical components of an MDI as of the priority date. As I explain in my Opening Reports, many inhalation aerosol devices, including metered dose inhalers, did not include any dose indicating mechanism at all; and many of those that did included dose indicators rather than dose counters—a design choice resulting from the difficulty of developing a dose counter with the necessary qualities. *See* Lewis Opening Reps. §§ IX.A.1-2, B; *see also infra* Section V.

176. I note that Mr. Anderson does not rely on the '102 Publication as a basis for asserting that any of the specific limitations required by the Asserted Claims are anticipated or obvious. And indeed, the '102 Publication teaches away from many of those limitations. For example, consistent with the prior art as a whole, many of the embodiments depicted in the '102 Publication appear to describe dose indicators, rather than dose counters. *See, e.g.,* '102 Publication, ¶¶ [0001]-[0007], Figs. 1-4, 21.

177. Additionally, consistent with the prior art as a whole, the '102 Publication emphasizes the dangers of undercounting relative to overcounting. Thus, the '102 Publication states: "[I]n order to avoid any risk of under-counting, it is generally necessary for the counter to

be actuated before or at the beginning of the actuation stroke of the valve or of the pump, so as to avoid any partial actuation that dispenses a partial or a complete dose, but that is not counted by the indicator.” ’102 Publication, ¶ [0002].

178. More generally, the ’102 Publication describes the difficulties of integrating a dose indicating mechanism into an inhaler, explaining that the small “tolerances of the device tend to reduce even further the effective distance available in order to perform the actuation reduce even further the effective distance,” requiring the use of a “complex mechanism.” ’102 Publication, ¶ [0002].

179. Notably, the ’102 Publication does not disclose any embodiments comprising a canister housing that has inner wall canister support formations (such as support rails) and a dose counter. The ’102 Publication’s disclosure of a dose counter and a canister housing without discussing any inner wall canister support formation is consistent with my opinion that the POSA would not have understood such features to be ubiquitous in the prior art, and is consistent with my opinion that the POSA would not have appreciated, based on prior art teachings, that the location of inner wall canister support formations relative to features of the dose counter could improve counter accuracy. The ’102 Publication also fails to disclose additional aspects of the Asserted Claims, including but not limited to the precise location of the dose counter relative to a datum plane passing through a shoulder of the valve stem block, or a regulator, as recited in the Asserted Claims.

V. Mr. Anderson’s “Background of the Relevant Technology” and “Summary of Motivations to Combine Prior Art References”

180. Mr. Anderson makes a number of general assertions about the prior art references upon which he relies, and the manner in which the POSA would allegedly have combined those references to render the Asserted Claims obvious. *See* Anderson Opening Rep. §§ X, XIV.B. I

disagree with his assertions.

181. Mr. Anderson's "Background of the Relevant Technology" oversimplifies the history of inhalation aerosol devices, such as metered dose inhalers ("MDIs"), and their design. In particular, Mr. Anderson points to the history of MDIs in an apparent effort to downplay the difficulty that individuals involved in the design of MDIs, such as the inventors and myself, faced as of the priority date. *See* Anderson Opening Rep. ¶¶ 47-52. For example, although Mr. Anderson states that "MDIs generally share a number of common structural traits," such as an aerosol canister, valve, valve stem, and valve stem block, as I explain in the Section above and throughout my report, MDIs and other inhalation aerosol devices differed greatly with respect to the design and placement of those components. Thus, in my opinion, the fact that specific examples of those components or groups of those components existed in certain devices does not entail that it would have been obvious to combine those components in a different manner. To the contrary, as I explain below and throughout my report, it would not have been obvious to do so.

182. Additionally, I disagree with Mr. Anderson's discussion of the history of "support rails" or "ribs" in the canister-receiving portion of MDIs, including his selective quotation from my article on inhaler design. *See* Anderson Opening Rep. §§ 50-51 (quoting Lewis 2007, at 236, CIPLA-BDI_0184749). Although it is true, as I wrote, that certain devices have included "support rails" or "ribs," as I explain throughout my report, the inclusion and placement of such features varied greatly as of the priority date and today. Indeed, many commercially available MDIs do not include such features, much less in the precise manner required by the Asserted Claims of the '289 and '587 Patents. *See, e.g., infra* Section VI.A. I therefore disagree with his suggestion that such features would have been obvious.

183. Likewise, I disagree with Mr. Anderson's discussion of dose counters and dose

indicators. *See* Anderson Opening Rep. ¶ 52. As I explain below and throughout this report, the use of such components was neither ubiquitous nor uniform, and the inclusion and design of such components, like the others discussed above, differed greatly.

184. Mr. Anderson's purported distinction between "tape-based dose counters" and "gear-based dose counters" is also inaccurate. *See* Anderson Opening Rep. ¶¶ 53-54. I do not dispute that certain mechanical dose counters use tape to display certain information and that other mechanical dose counters use gears or other mechanisms. However, the POSA would not understand mechanical dose counters to fall into distinct categories, such as "tape-based dose counters" and "gear-based dose counters." Instead, as the examples Mr. Anderson provides reflect, the POSA would understand that mechanical dose counters, like other devices, used a variety of mechanisms to display information and that those mechanisms could be adapted for use in a variety of different inhalation products.

185. Additionally, I disagree with Mr. Anderson's "Summary of Motivations to Combine Prior Art References." In particular, I disagree with Mr. Anderson's opinion that "each of the Asserted Claims simply arranges elements ubiquitous in the prior art, with each performing the same function it had been known to perform at the time of the invention." Anderson Opening Rep. ¶ 100. I also disagree that the Asserted Claims reflect no more than what the POSA would have expected to obtain by combining the prior art elements Mr. Anderson identifies.

186. To the contrary, I disagree that dose counters were ubiquitous in the prior art as of the priority date of the Asserted Claims. *See* Anderson Opening Rep. ¶ 100. As I discussed in my Opening Reports and as I note in my analysis of Mr. Anderson's alleged prior art, many prior art inhalers contained no dose counting or dose indicating mechanism at all. *See, e.g.,* Lewis Opening

Rep. (Cipla) ¶¶ 415-23.¹ I incorporate by reference my analysis of the alleged prior art references in Section IV as though set forth herein, and do not repeat it here solely for the sake of brevity. Among those inhalers that did contain a mechanism for tracking doses, most were imprecise dose indicators, not dose counters. *See, e.g.,* Lewis Opening Rep. (Cipla) ¶ 425.

187. Other inhalers had “add on” dose counters or dose indicators that were external to the canister housing and often exposed to patients. *See, e.g.,* Lewis Opening Rep. (Cipla) ¶¶ 426-31. These “add on” devices avoided the challenge of incorporating a dose counter into the canister housing, but were often bulky and/or prone to tampering and damage. *See, e.g.,* Lewis Opening Rep. (Cipla) ¶¶ 426-31.

188. Indeed, the first MDI with a dose counter was not launched until 2004 in the form of GlaxoSmithKline’s Seretide in Europe. *See, e.g.,* Lewis at 240, CIPLA-BDI_0184747, at -753; Stein 2013, at 334. Even today, “there are still pMDI devices on the market that do not have a dose counter despite FDA guidance in 2003.” Usmani 2019, at 464. Just as dose counters were not ubiquitous, neither were any particular components of dose counters or locations of dose counters.

189. Likewise, other components on which Mr. Anderson focuses were not “ubiquitous.” For example, the “inner wall canister support formation” limitation of the claims of the ’289 and ’587 Patents were not ubiquitous—as of the priority date, many references describing inhalers did not describe or depict “inner wall canister support formations” (which typically take the form of “support rails” “ribs” in the canister housing). I reviewed many of these references in my discussion of the “Alleged Prior Art” above, and I incorporate that discussion in Section IV as

¹ For convenience, I cite the relevant paragraphs in my Opening Report as to Cipla. My Opening Report as to Aurobindo contains materially similar opinions.

though set forth fully herein. For example but not by way of limitation, references upon which Mr. Anderson relies that do not include “ribs” at all (or omit “ribs” in embodiments disclosing dose counters) include the ’406 Publication (depicting and describing inhalers without rails extending outwardly from the main body); the ’044 Publication (same); ’817 Publication (same); ’021 Publication (same); ’191 Publication (Figures 31, 32, 70, 71, 73-76, 93, 136, depicting a canister housing without support rails); the ’552 Publication, the ’950 Publication, the ’627 Patent, GB ’489, the ’159 Publication, the ’965 Publication, and the ’102 Publication (as I explained in detail above in Section IV, which I incorporate by reference here as though fully set forth herein). Other references described such ribs as optional. *See* ’008 Publication, ¶ [0045] (“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”). Publication, ’Other references described such ribs as optional. *See* ’008 Publication, ¶ [0045] (“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”); *see also* ’514 Publication at 14:17-19; ’822 Patent, 3:11-14. Even today, inhalers are marketed without “inner wall canister support formations”—i.e., support rails. *See* Exhibit B.

190. I also disagree that the claimed inventions merely reflect the combination of elements known in the art, with “each performing the same function it had been known to perform at the time of the invention, and the combination yields no more than what a person of skill in the art would expect from such an arrangement.” Anderson Opening Rep. ¶ 100. To the contrary, “[t]o the untrained eye, it may appear that adding a dose counter or indicator to a metered dose inhaler is a simple task, but there are a number of technical challenges and complex factors that

need to be assessed.” Stuart 2013, at 40, TEVADOC-00000531.² In dose counters that are actuated by the displacement of the MDI valve, they must contend with the “small amount of travel available to count in and the requirement to match valve travels—both of which can make designing and controlling the manufacturing process a challenge.” Stuart 2013 at 41, TEVADOC-00000532. “Matching a dose counter to a valve’s travels is difficult due to the large manufacturing tolerances and small window of operation.” Stuart 2013 at 43, TEVADOC-00000534. Likewise, the counter must be small enough to be portable but large enough to be functional and readable. Indeed, “[a] product with a high number of doses will often be pushed to a dose indicator—an indicator is often the only choice when it is difficult to fit a numerical display that can count down in individual increments from 200 doses within the space limitation of a conventional MDI actuator.” Stuart 2013 at 43, TEVADOC-00000534.

191. It is also a challenge to design a counter that is robust—namely one that is accurate, robust to dropping, and tamper proof. Stuart 2013, at 42, TEVADOC-00000533. Furthermore, any counter must be designed to avoid interfering with dose delivery. “There are obvious aesthetic advantages of an internal dose counter or indicator, but its location creates the risk of affecting airflow through the MDI.” Stuart 2013, at 43, TEVADOC-00000534.

192. Contrary to the premise of Mr. Anderson’s opinion, it is simply not the case that any dose counter could be combined with any canister or any valve stem or any canister housing. To the contrary, the POSA would have understood that integrating a dose counter into a MDI or other inhalation aerosol product would require adapting inhaler and counter components to one another. [REDACTED]

² I note that Stuart was published in 2013, after the priority date to which the Asserted Patents are entitled. Nevertheless, in my opinion, Stuart’s retrospective analysis written shortly after the priority date accurately reflects the considerations the POSA would have faced as of 2011.

[REDACTED]

193. I also disagree that the inventions of the Asserted Claims were merely responses to well-recognized design needs and market pressures. To the contrary, and as the prior art reflects, “pharmaceutical companies are often deterred from adding a dose counter or indicator to a metered dose inhaler (MDI) due to the associated complexity and costs.” Stuart 2013, at 40, TEVADOC-00000531.

194. Even if the POSA had reason to add a dose counter to an MDI and/or improve its accuracy with a reasonable expectation of success, the POSA would have faced many decision points, including but not limited to: (1) whether to use a dose counter or a dose indicator, (2) how to actuate the counter/indicator, and (3) where to locate the counter/indicator with respect to the inhaler. *See, e.g.*, Stuart 2013, at 40-41, TEVADOC-00000531-532. Only a POSA who chose to create a dose counter that actuated by movement of the canister valve/body and located low in the canister housing would have even faced the specific set of problems that the claimed inventions

are designed to solve. The POSA who made a different choice at any juncture would not have faced these problems and thus would not have had reason to solve them or reasonably expected to succeed in doing so.

195. Furthermore, even if the POSA chose to create a dose counter that was actuated by movement of the canister valve/body and located low in the canister housing, he or she would not have arrived at the claimed inventions. As the prior art reflects, other solutions to the problems that arise from these circumstances were available. For example, GlaxoSmithKline developed a dose counter that was similarly positioned, but addressed issues of unwanted actuation in an entirely different manner than the claimed inventions—namely, by affixing the counter to the canister so that one could not move relative to the other. *See, e.g.*, '514 Publication. Such a design would need to be tailored to the canister, valve stem, and canister housing utilized. I thus disagree that there are “a finite number of predictable solutions to problems known in dose counters.” Anderson Opening Rep. ¶ 102.

VI. Mr. Anderson’s Invalidity Theories Are Incorrect

A. The '289 and '587 Patents

196. Mr. Anderson opines that Asserted Claims 1-8 of the '289 Patent and Asserted Claims 1-8, and 11-22 of the '587 Patent are anticipated or would have been obvious over various prior art references. I disagree with his opinions for the reasons I explain below.

197. In the context of these opinions, I understand as explained above that the parties have agreed that certain terms should carry certain meanings. As relevant here, I am informed those terms and meanings are:

<u>No.</u>	<u>Term</u>	<u>Agreed-Upon Construction</u>
1	“canister housing”	“the portion of the inhaler body that is arranged to retain a medicament canister”

<u>No.</u>	<u>Term</u>	<u>Agreed-Upon Construction</u>
5	“canister support formation” 5	“a formation arranged to reduce canister rocking”
6	“actuator”	“A structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component.”
13	“main surface of the inner wall”	“inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament”
14	“inner wall through which a portion of the actuation member extends	“an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament”
15	“inner wall”	“an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body”
16	“protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler”	“guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter’s actuator enough to cause unwanted incrementing (or decrementing) of the dose counter”

See Joint Claim Construction Chart 3-5.

198. In addition, I have been informed that the parties dispute the meaning of the

following claim terms in the '289 and '587 Patents and that the Court has yet to rule on these disputes. Accordingly, I have applied both parties' constructions in forming my opinions. In my opinion, and as explained in this report, the Asserted Claims are not invalid under either side's proposed constructions.

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
1	<p>"actuation member"</p> <p>'289 Patent, claims 1, 3</p> <p>'587 Patent, claims 1, 3, 11, 12, 13</p> <p>'156 patent, claims 12</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>"a component of the dose counter's actuator that transmits motion from the canister to the actuator"</p>	<p>"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"</p>
2	<p>"[lying or lie] in a common plane coincident with the longitudinal axis X"</p> <p>'289 Patent, claim 1</p> <p>'587 Patent, claims 1, 12, 21, 22</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.</p>	<p>"aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"</p>
3	<p>"positioned at opposite ends of the inside surface of the main body to face each other"</p> <p>'289 Patent, claim 7</p> <p>'587 Patent, claims 7, 18</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>"located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other"</p>	<p>"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"</p>

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
4	<p>“step[(s)] formed thereon”</p> <p>’289 Patent, claims 5, 8</p> <p>’587 Patent, claims: 5, 8, 16, 19</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“a location of changing width dimension thereon”</p>	<p>“A stepwise increase in the extent to which the support rail extends inwardly”</p>
10	<p>“the body”</p> <p>’156 Patent, claim 12</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“inhaler body” - ’156 Patent, 22:64, 67</p> <p>“dose counter body” - ’156 Patent, 22:66</p>	<p>This term is indefinite.</p>
11	<p>“counter display arranged to indicate dosage information”</p> <p>’808 Patent, claim 1</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“a component of the dose counter that displays information regarding the number of doses remaining”</p>	<p>“structure displaying the number of doses remaining”</p>
12	<p>“first station”</p> <p>’808 Patent, claim 1</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“a first region”</p>	<p>“first structure on which the counter is located”</p>
14	<p>“aperture”</p> <p>’289 Patent, claim 3</p> <p>’587 Patent, claims 3, 13, 20-22</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“an opening or open space: hole”</p>	<p>“hole”</p>

See Joint Claim Construction Chart 6-10.

1. Mr. Anderson's Anticipation Theories Are Incorrect

199. Mr. Anderson sets forth two anticipation theories. For the reasons I explain below, neither is correct. Neither the '406 Publication nor the '514 Publication discloses every limitation of any Asserted Claim of the '289 or '587 Patents, let alone as arranged in those Asserted Claims.

a. The '406 Publication Does Not Anticipate the Asserted Claims of the '289 and '587 Patents

1) The '289 Patent

200. Mr. Anderson asserts that the '406 Publication anticipates Asserted Claims 1-3 of the '289 Patent. I disagree, and I incorporate by reference my analysis of the '406 Publication in Section IV.A as though fully set forth herein. I have not reproduced it here solely for the sake of brevity.

201. Asserted Claim 1 of the '289 Patent recites as follows:

1. An inhaler for metered dose inhalation, the inhaler comprising:
 - a main body having a canister housing,
 - a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
 - a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

a) Claim 1

202. The '406 Publication fails to disclose every limitation of Asserted Claim 1 of the '289 Patent as arranged in the claim.

203. As a preliminary matter, the '406 Publication describes five distinct dose counters

that can be used in an inhaler. One dose counter is described in Paragraphs [0090]-[00116] in conjunction with Figures 1-11. A second dose counter is described in Paragraphs [00117]-[00134] in conjunction with Figures 12-20. A third dose counter is described in paragraphs [00135]-[00159] in conjunction with Figures 21-30. A fourth dose counter is described in paragraphs [00160]-[00170] in conjunction with Figures 31-40. A fifth dose counter is described in paragraphs [00171]-[00182] in conjunction with Figures 41-47.

204. Mr. Anderson's opinion that the '406 Publication discloses every limitation of Asserted Claim 1 of the '289 Patent mixes and matches various disclosures from these five separate examples indiscriminately. For example, Mr. Anderson incorrectly applies descriptions of "wings" in the first and second embodiments to "forward legs" of the third embodiment. I do not agree with this approach, because the '406 Publication describes these embodiments as different dose counters, and the POSA would not understand a feature of one dose counter to be interchangeable with a feature of another. The POSA would understand that the components of a particular dose counter embodiments work together, and that mixing and matching components from one embodiment to another would be contrary to the POSA's understanding of a reference's disclosure and experience and expertise in the field. Indeed, the disclosure in the '406 Publication of five distinct dose counters, none of which individually embodies the claimed inventions (as Mr. Anderson acknowledges in mixing and matching components from different dose counters disclosed in the reference), reinforces the novelty of Asserted Claim 1.

205. In addition, I disagree with Mr. Anderson that the '406 Publication discloses an inner wall canister support formation. Mr. Anderson states that "the dose counter housing includes two forward legs (378) which mate with 'interior surfaces of the actuator housing for the aerosol container.'" Anderson Opening Rep. ¶ 120. Mr. Anderson asserts that "[i]n order to 'mate' there

must be a formation extending inwardly from a main surface of the inner wall. Such a formation would act as a canister support formation.” Anderson Opening Rep. ¶ 120. In other words, Mr. Anderson appears to suggest that, although the ’406 Publication does not disclose expressly a “canister support formation,” that limitation is necessarily present in the ’406 Publication by virtue of its disclosure of the forward legs (378). I disagree with Mr. Anderson.

206. The “forward legs (378)” to which Mr. Anderson refers are depicted in Figures 23-25 and 28, which describe the third exemplary dose counter of the ’406 Publication. I have reproduced Figure 28 of the ’406 Publication below, with item 378 indicated in blue.

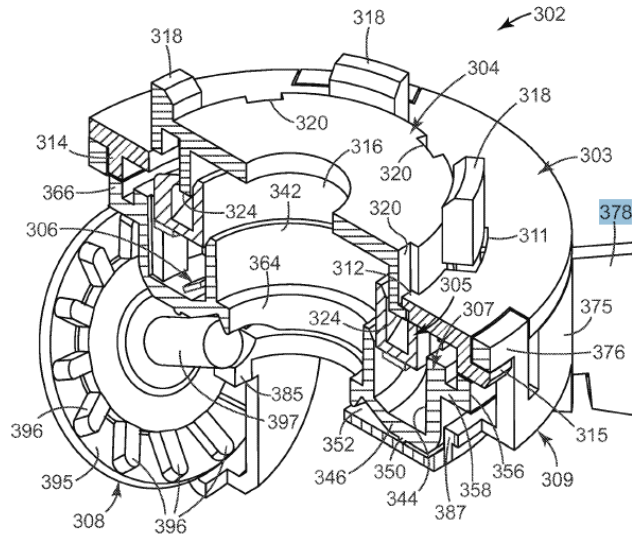


FIG. 28

207. In support of his assertions that “forward legs (378)” would “mate” with an inner wall canister support formation, Mr. Anderson does not identify any Figure of the ’406 Publication that shows such an interaction (nor could he do so, since no Figure does). Instead, he refers to paragraph 143 of the ’406 Publication. Anderson Opening Rep. ¶ 120. That paragraph contains the only description of feature 378 that appears anywhere in the ’406 Publication—it states that “[t]he [dose counter] housing 309 has a generally cylindrical body 375 with a plurality (e.g., three) of doorframe features 376, two forward legs 378 and a viewing window 379 thereon.” ’406

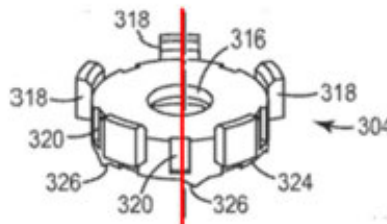
Publication, [00143]. Mr. Anderson's assertion that forward legs 378 mate with "interior surfaces of the actuator housing for the aerosol container 70" is incorrect. *See* Anderson Opening Rep. ¶ 120. This quotation comes from paragraphs [00100] (describing the mating of "wings 64" in the first embodiment, as depicted in Figure 3) and paragraph [00119] (describing the mating of "wings 264" in the second embodiment, as depicted in Figure 16). '406 Publication, ¶¶ [00100], [00119]. Contrary to Mr. Anderson's suggestion, there is no description in the '406 Publication of the "forward legs 378" mating with anything.

208. Even were the POSA to assume that statements regarding the wings of the first and second embodiments described by the '406 Publication were equally applicable to "forward legs 378" of the third embodiment of the '406 Publication (and, to be clear, the '406 Publication provides no such disclosure, and the POSA would not have done so), the POSA would not have understood any feature that "mated" with forward legs (378) of the '406 Publication to be an inner wall canister support formation. To the contrary, it is plain that any feature that interacts with forward legs 378 would be a feature on which those legs rest—that is evident by the upside-down facing "hook" shape of those legs (as shown in Figure 28, reproduced above, which Mr. Anderson's report does not address in connection with this argument), designed to attach to a feature extending upwardly from the base of the inhaler, not outwardly from the inhaler's inner wall. Such a feature is not an "*inner wall* canister support formation" nor is it "a formation arranged to reduce canister rocking"—the parties' agreed upon construction for "canister support formation." Such a feature would not even extend to the portion of the canister housing in which the canister resides nor would it interact with the canister in any way; it most certainly would not do so always and necessarily. The wings and legs of the other dose counter embodiments described in the '406 Publication each have a slightly different shape (further confirming the impropriety of

mixing and matching components from the various embodiments), but none is configured to interact with an “inner wall canister support formation.”

209. Because the '406 Publication does not disclose an “inner wall canister support formation” it cannot disclose the final limitation of Asserted Claim 1 of the '289 Patent: “the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X” (“Common Plane Limitation”). Mr. Anderson’s opinion to the contrary is deeply flawed, for at least the reasons set forth above and below.

210. First, Mr. Anderson suggests that, because the castellations of the indexer of the '406 Publication are arranged in a circle around the central outlet port, “any support structure will necessarily lie in a common plane” with that circle—by way of illustration, he provides the following image:



Anderson Opening Rep. ¶ 123.

211. At the outset, I do not understand Mr. Anderson’s reference to “any support structure.” As I discussed above, the '406 Publication does not disclose an “inner wall canister support formation” and thus there is no such structure disclosed in the '406 Publication (let alone one identified as an inner wall canister support formation in Mr. Anderson’s report) that could lie in a common plane with the central outlet port and actuation member. Furthermore, it is not accurate to suggest that the castellations of the indexer (the actuation member(s)) entirely encircle

the central outlet port. While Mr. Anderson has conveniently (and arbitrarily, without any stated basis in the '406 Publication) drawn a line through the center of the central outlet port that does intersect one castellation, there are many such lines that can be drawn through the center of the central outlet port that do not intersect a castellation, because the castellations do not extend around the entire diameter of the indexer. Thus, it is not accurate to say that the (nonexistent, unidentified) inner wall canister support formation would necessarily lie in a common plane with the central outlet port and a castellation of the indexer.

212. Mr. Anderson also asserts that the forward legs (378) of the third dose counter example in the '406 Publication are in a common plane with the central outlet port and a castellation of the dose counter shown in the '406 Publication. He illustrates this position with the following image:

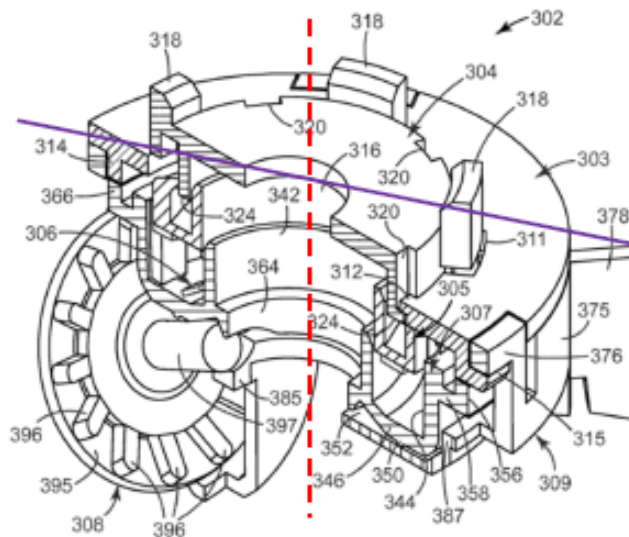


FIG. 28

Anderson Opening Rep. ¶ 124.

213. First, as I have explained above, I disagree that legs (378) reflect the position of any inner wall canister support formation; I do not even understand Mr. Anderson to assert that the legs (378) themselves constitute an inner wall canister support formation. Even were I to set

that deficiency in Mr. Anderson's analysis aside, however, I disagree that Figure 28 (or any image in the '406 Publication) permits the POSA to understand whether legs (378) are in a common plane with a castellation of the indexer and the central outlet port. Certainly, Figure 28 does not permit the POSA to understand where a completely undisclosed an inner wall canister support formation would be located, let alone its shape, configuration, or dimensions.

Regardless, Figure 28 does not show the correct perspective from which to determine whether the elements it does depict (and again, these do not include an inner wall canister support formation) lie in a common plane. In order to understand whether a straight line can be drawn to connect legs (378) with the center of the central outlet port and a castellation, the POSA would need a view of the inhaler looking down longitudinal axis X. From the perspective shown in Figure 28, the purple line Mr. Anderson has drawn does not even pass through the center of the central outlet port, and it is not clear whether leg 378 is "behind" or "inline" with castellation 318. In light of the above, it is my opinion that the '406 Publication does not disclose every limitation of Asserted Claim 1 of the '289 Patent or every limitation as arranged in the claim.

b) Claim 2

214. Asserted Claim 2 depends from Asserted Claim 1 and recites: "The inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." In my opinion, at a minimum, the '406 Publication does not disclose a "dose counter as claimed in claim 1." *See supra* Section VI.A.1.a.1)a). Thus, the '406 Publication does not anticipate this claim.

c) Claim 3

215. Asserted Claim 3 depends from Asserted Claim 1 and recites: "The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." In my opinion, at a minimum, the '406 Publication

does not disclose a “dose counter as claimed in claim 1.” *See supra* Section VI.A.1.a.1)a). Thus, the ’406 Publication does not anticipate this claim.

2) The ’587 Patent

216. Mr. Anderson asserts that the ’406 Publication anticipates Asserted Claims of the ’587 Patent. I disagree, and I incorporate by reference my analysis of the ’406 Publication in Section IV.A as though fully set forth herein. I have not reproduced it here solely for the sake of brevity.

a) Claim 1

217. Claim 1 of the ’587 Patent recites as follows:

1. An inhaler for metered dose inhalation, the inhaler comprising:
 - a main body having a canister housing,
 - a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
 - a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
 - wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X **such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler**

Asserted Claim 1 of the ’587 Patent is materially identical to Asserted Claim 1 of the ’289 Patent, except that Asserted Claim 1 of the ’587 Patent adds the additional limitation I have underlined in bold type above, which requires that “the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

218. Because Asserted Claim 1 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that the '406 Publication does not disclose every limitation of Asserted Claim 1 of the '587 Patent. I incorporate all of those reasons set forth in Section VI.A.1.a.1)a) above into this Section, as if set forth fully herein. I have not repeated them solely for the sake of brevity.

219. Furthermore, the '406 Publication fails to anticipate Asserted Claim 1 of the '587 Patent because the '406 Publication does not disclose “that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

220. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '406 Publication because the '406 Publication “discloses every structural element” of the claim and these structure elements necessarily “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” *See* Anderson Opening Rep. ¶ 133.

221. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler) that the Asserted Claims of the '289 Patent do not require.

222. Regardless, I disagree that the '406 Publication “discloses every structural element” of the claim—as I described above, the '406 Publication fails to disclose an inner wall canister support formation, let alone that such an inner wall canister support formation lies in a common plane with the central outlet port and actuation member of the dose counter.

223. I also disagree that the mere presence of an inner wall canister support formation

that lies in a common plane with the central outlet port and the actuation member of the dose counter—without any disclosure (which Mr. Anderson does not dispute is lacking) regarding the size, shape, or other properties of the inner wall canister support formation—is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” Again, Mr. Anderson does not dispute that the ’406 Publication does not contain any disclosure of this limitation; he rather asserts that this limitation is inherent in what the ’406 Publication does disclose. I have been informed that for a reference to inherently disclose a limitation such a limitation must be necessarily present in or naturally result from the disclosed embodiment. By contrast, I understand a limitation that *may* result or *may* be present in a disclosure is not sufficient for purposes of inherency. Not every support rail, inhaler, and canister combination that satisfied the common plane limitation (even assuming the ’406 Publication disclosed all of those components, which it does not) would meet the claimed requirement to “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” I do not understand Mr. Anderson to have provided any actual analysis to support any conclusion to the contrary. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation, because the claimed function does not result necessarily from the structural components recited in the claim.

224. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



225. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

b) Claim 2

226. Asserted Claim 2 depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter.” In my opinion, at a minimum, the ’406 Publication does not disclose a “dose counter as claimed in claim 1.” *See supra* Section VI.A.1.a.2)a). Thus, the ’406 Publication does not anticipate this claim.

c) Claim 3

227. Asserted Claim 3 depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.” In my opinion, at a minimum, the ’406 Publication does not disclose a “dose counter as claimed in claim 1.” *See supra* VI.A.1.a.2)a). Thus, the ’406 Publication does not anticipate this claim.

d) Claim 12

228. Asserted Claim 12 of the ’587 Patent recites as follows:

12. An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X **such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.**

Asserted Claim 12 of the ’587 Patent is materially identical to Asserted Claim 1 of the ’289 Patent, except that Asserted Claim 12 of the ’587 Patent adds the additional limitation I have underlined in bold type above, which requires that “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away

from the actuation member.”

229. Because Asserted Claim 12 of the ’587 Patent contains every limitation of Asserted Claim 1 of the ’289 Patent, I conclude for the reasons I described above that the ’406 Publication does not disclose every limitation of Asserted Claim 12 of the ’587 Patent. I incorporate all of those reasons set forth in Section VI.A.1.a.1)a) above into this Section, as if set forth fully herein. I have not repeated them solely for the sake of brevity.

230. Furthermore, the ’406 Publication fails to anticipate Asserted Claim 12 of the ’587 Patent because the ’406 Publication does not disclose “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

231. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the ’406 Publication because the ’406 Publication “discloses every structural element” of the claim and these structure elements necessarily protect against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. Anderson Opening Rep. ¶ 133.

232. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member) that the Asserted Claims of the ’289 Patent do not require.

233. Regardless, I disagree that the ’406 Publication “discloses every structural element” of the claim—as I described above, the ’406 Publication fails to disclose an inner wall canister support formation, let alone that such an inner wall canister support formation lies in a common plane with the central outlet port and actuation member of the dose counter.

234. Mr. Anderson does not address Asserted Claim 12 in his report separately from the manner in which he addresses Asserted Claim 1. This failure further undermines Mr. Anderson's opinion, as the requirements of Asserted Claim 1 and Asserted Claim 12 are distinct. Claim 1 requires "reducing rocking of the medicament canister relative to the main body of the inhaler" while Asserted Claim 12 requires "reducing rocking of the medicament canister towards or away from the actuation member." As the POSA would have understood, certain support rail configurations could achieve the first of these requirements without achieving the second. Nothing in the '406 Publication discloses an inner wall canister support formation that prevents rocking of the canister towards or away from the actuation member.

235. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter—without any disclosure (which Mr. Anderson does not dispute is lacking) regarding the size, shape, or other properties of the inner wall canister support formation—is sufficient to establish that the arrangement will "protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member." Again, Mr. Anderson does not dispute that the '406 Publication does not contain any disclosure of this limitation; he rather asserts that this limitation is inherent in what the '406 Publication does disclose. I have been informed that for a reference to inherently disclose a limitation such a limitation must be necessarily present in or naturally result from the disclosed embodiment. By contrast, I understand a limitation that *may* result or *may* be present in a disclosure is not sufficient for purposes of inherency. Not every support rail, inhaler, and canister combination that satisfied the common plane limitation (even assuming the '406 Publication disclosed all of those components, which it does not) would meet the claimed requirement to "protect against unwanted

actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member.” I do not understand Mr. Anderson to have provided any actual analysis to support any conclusion to the contrary. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation, because the claimed function does not result necessarily from the structural components recited in the claim.

236. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



237. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely

tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

b. The '514 Publication Does Not Anticipate the Asserted Claims of the '289 and '587 Patents

1) The '289 Patent

238. Mr. Anderson asserts that the '514 Publication anticipates Asserted Claims of the '289 Patent. I disagree, and I incorporate by reference my analysis of the '514 Publication in Section IV.C as though fully set forth herein. I have not reproduced that section here solely for the sake of brevity.

a) Claim 1

239. Mr. Anderson asserts that Asserted Claims 1 and 4-8 of the '289 Patent are anticipated by the '514 Publication. I disagree. The '514 Publication does not disclose every limitation of Asserted Claim 1 as arranged in that claim.

240. As a preliminary matter, the '514 Publication describes several different embodiments of dose indicators, dose counters, and canister housings. For example, the canister housings shown in Figures 2b, 3, 8b, and 10 do not contain support rails, while those in some other Figures do. The '514 Publication also describes embodiments in which the annular dose tracking mechanism that is the focus of the '514 Publication's disclosure is a dose indicator and others in which it is a dose counter. *See* '514 Publication, 19:11-13. In particular, the '514 Publication states that the “indicia” that display dose information may be “alphabetical, numerical, alphanumeric, or color symbols, providing a sequential count-up or count-down of dispensed doses or providing a more general indication, such as ‘Full’, ‘Empty’, etc.” '514 Publication, 19:11-13. Some embodiments described in the '514 Publication are metered dose inhalers, while others are breath actuated inhalers. *See* '514 Publication, 6:16-20. The dose counter operates by moving

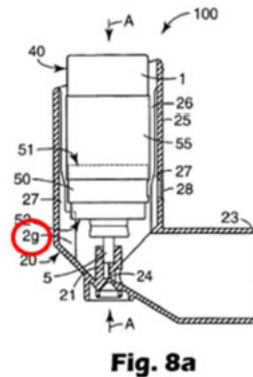
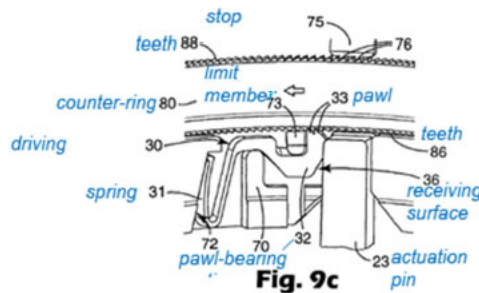
downwards when the patient dispenses medication—it then strikes a component of the canister housing, that interacts with features of the dose indicator to cause it to increment. ’514 Publication, 26:5-19. In some embodiments, the feature of the canister housing that strikes a component of the dose indicator is an “actuation pin” which is “typically” a “form-molded element of the adaptor” and in some embodiments is an “extension of a rib” but in other embodiments is a stand-alone feature. ’514 Publication, 25:17-20; Figures 8a, 8b, 10. Mr. Anderson’s opinion conflates all of these embodiments—for example, in his anticipation theory for claim 1, he relies on disclosures from in each of Figure 2a (which discloses a canister housing that has not been modified to accommodate the annular dose counter described in the ’514 Publication, Figure 8a, which shows a housing designed to accommodate the annular dose counter), Figure 11 (which shows “another preferred embodiment of a dispenser”), and Figure 12a (which shows “an additional preferred embodiment of a dispenser”). The POSA would understand that Figure 2a corresponds to a different embodiment than Figure 8a which corresponds to a different embodiment than Figure 11a, which corresponds to a different embodiment than Figure 12a. Moreover, the POSA would understand that the components of particular embodiments work together, and that mixing and matching components from one embodiment to another would be contrary to the POSA’s understanding of a reference’s disclosure and experience and expertise in the field.

241. In particular, Mr. Anderson appears to assume that Figures 8a and 9c reflect embodiments of the ’514 Publication that are dose counters rather than dose indicators. Nothing in these images or their description suggests this to be the case. To the contrary, Figure 9 depicts “an enlarged, partial view of the preferred dispensers depicted in Figures 8a and 8b, showing the region of the driving member of the dose indicator at various dispensing positions” while Figure 8 shows a “vertical cross-sectional views of two preferred embodiments of a dispenser comprising

a canister-indicator assembly illustrated in Figure 7.” ’514 Publication, 12:8-14. Figure 7, in turn, “shows a cross sectional view of the preferred annular dose indicator illustrated in Figures 5 and 6, mounted and attached to a dispensing canister of the type depicted in Figure 1a, providing a preferred embodiment of a canister-indicator assembly.” ’514 Publication, 12:4-6. And Figure 5 plainly depicts a dose indicator, not a dose counter, because it is arranged to display to the patient the number of doses remaining or expended only in increments of 10. ’514 Publication, Figure 5. The embodiments depicted in Figures 8a and 9c therefore correspond to a dose indicator, not a dose counter as Asserted Claim 1 requires. Accordingly, I conclude that it does not anticipate Asserted Claim 1, nor does any other embodiment in the ’514 Publication.

242. Furthermore, nothing in Figure 9c, on which Mr. Anderson relies, indicates whether it is associated with a metered dose inhaler (as the claims require) or a breath- actuated inhaler, which is not consistent with the claimed invention. Accordingly, that embodiment does not anticipate Asserted Claim 1, nor does any other embodiment in the ’514 Publication.

243. The ’514 Publication also fails to disclose an actuation member within the meaning of Asserted Claim 1. Mr. Anderson asserts that Figure 8a of the ’514 Publication contains an “actuation pin” labeled 2g. Anderson Opening Rep. ¶¶ 139-140. Mr. Anderson asserts this is the same feature labeled 23 in Figure 9c, and that is referred to as element 29 in the text of the ’514 Publication. I reproduce Mr. Anderson’s annotated versions of those figures below, but I disagree with his conclusion and his labels. The structures that Mr. Anderson identifies are not part of the dose counter, as Asserted Claim 1 requires, and are not an “actuation member” within the meaning of Asserted Claim 1.

**Fig. 8a****Fig. 9c**

244. The '514 Publication never explains the identity or purpose of element 2g in Figure 8a or element 23 in Figure 9c—there is no reference to these structures anywhere in the '514 Publication. There is no disclosure that either of these elements constitutes an actuation pin, which is why Mr. Anderson has to provide his own annotations to the figures, because he cannot point to anything in the '514 Publication that describes them. Mr. Anderson asserts without basis that structure 2g in Figure 8a and structure 23 in Figure 9c are in fact the same structure, and that both are the “actuation pin” referred to as feature 29 in the body of the '514 Publication. Anderson Opening Rep. ¶¶ 139-40. Again, the '514 Publication says no such thing. I do not agree that Mr. Anderson's conclusion is supported, because the '514 Publication is simply silent as to these features. Absent actual disclosure in the reference, which Mr. Anderson agrees is lacking, the POSA would not have assumed two different labels in two different figures to refer to the same structure, and then further assumed these two structures correspond to still a third label with a different number—structure “29”—as referenced in the text.

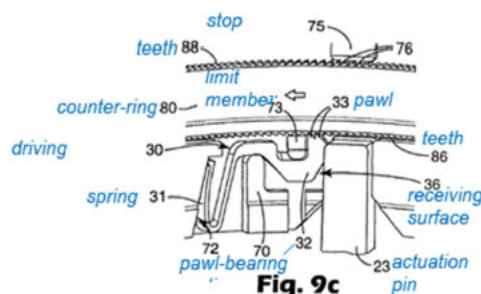
245. Nor would the POSA have understood that component 36 in Figure 9c should be interpreted as “inclined receiving surface 96” in the text. I understand the POSA interprets what actually is disclosed in the prior art, rather than rewriting it to disclose something different. Mr. Anderson's substitution of labels and decision to ignore what the '514 Publication actually

discloses appears to constitute the latter, rather than the former.

246. Furthermore, even assuming *arguendo* that the POSA somehow would have understood the '514 Publication to disclose that structure 2g in Figure 8a is structure 23 in Figure 9c is the “actuation pin (29)” of the text (and the POSA would not have so interpreted the document), this structure is not an actuation member of the dose counter, as Asserted Claim 1 requires. Nor is element 36 of Figure 9c (which again, the POSA would not have understood to be “inclined receiving surface 96” described in the text.

247. Asserted Claim 1 recites a “dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister.” The '514 Publication explains expressly that “actuation pin (29)” is part of the inhaler “adaptor” (i.e., canister housing), not part of the dose counter as Asserted Claim 1 requires. *See, e.g.*, '514 Publication, 25:17-20 (“More particularly, the adaptor is advantageously provided with an actuation pin (29), typically as a form-molded element of the adaptor. In the embodiment shown in Figure 8a, the actuation pin (29) is provided as an extension of a rib (27).”). Certainly, the feature Mr. Anderson has identified in Figure 8a and asserts to be the actuation pin (in contravention of the '514 Publication's text) is plainly part of the canister housing, not the dose indicator. I do not understand Mr. Anderson to assert that the '514 Publication's statement that the actuation pin is part of the canister housing to be yet another typo in the '514 Publication, nor does Mr. Anderson identify any embodiment in which the actuation member is not part of the canister housing. Nor would the POSA have envisioned such a combination of elements, as making this change to the embodiment depicted in the figures on which Mr. Anderson relies, would have created distinct configurations, and there is no basis to conclude that such a combination would have been operable with other elements of the claim.

248. Receiving surface 32 in figure 9c is not an “actuation member” within the meaning of Asserted Claim 1. I have reproduced Mr. Anderson’s annotated version of Figure 9c below (and I again note I do not agree with his annotations).



Regardless, even accepting *arguendo* Mr. Anderson’s assertion that element 36 of Figure 9c is the “inclined receiving surface 96” referenced in the text, that element does not extend out of the dose indicator of the ’514 Publication, and so does not have “at least a portion thereof located in the canister housing” as Asserted Claim 1 requires. As Figure 9c makes clear, element 36 is located fully within the dose indicator. The text of the ’514 Publication indicates that “inclined receiving surface (96)” is part of the “pawl-bearing portion (92) of the driving member (90)” and that “the counter-ring and driving member are located or mounted *within the housing of the indicator.*” ’514 Publication, Abstract, 4:18, 6:11-14, 26:5-7 (emphasis added). Accordingly, no portion of receiving surface (96) or component 36 of Figure 9c is “located in the canister housing.”

249. “Actuation pin” 29 or 2g or 23, alone or in combination with receiving surface 36 is also not an “actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister.” Structure 2g or 23 or 29 is not “operated by movement of the medicament canister” nor is it “operated” at all—it is a static form-molded part of the canister housing that does not move. It also never touches the medicament canister,

and thus is not “operated by movement of the medicament canister.” Likewise, structure 96 or 36 never touches the medication canister and so is not “operated by movement of the medicament canister.” Indeed, structure 96 or 36 is mounted to the dose indicator’s housing, which is in turn mounted to the medication canister, and therefore that structure *cannot* move relative to the medication canister. No component of the dose indicator of the ’514 Publication can be “operated by movement of the medicament canister,” as Asserted Claim 1 requires, because the dose indicator is affixed to the canister. *See, e.g.*, ’514 Publication, 4:22-23 (“wherein said indicator is arranged to be circumferentially mountable about the dispensing-canister”), 6:4-8 (“Annular dose indicators according to the invention are advantageous in that the indicator can be manufactured independent of the dispensing-canister and the adaptor to provide a self-contained assembly. They can be easily mounted around the dispensing canister by sliding the indicator over the outlet- or container-end of the dispensing canister, as the case may be.”), 7:16-24 (“Furthermore dose indicators, in particular the housing, can be advantageously secured to an external surface of the dispensing canister, preferably to an external surface of the container or, if applicable the ferrule of the dispensing canister, to provide a self-contained canister/indicator assembly. The provision of a dispensing-canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure means) and above the outlet means of the canister is particularly advantageous, because such an assembly is desirably robust.”), 8:6-14 (“an annular mechanical dose indicator mounted circumferentially about the dispensing-canister and secured to an external surface of the dispensing canister. . . . Preferably the indicator is secured to an external surface of the container. In particular the indicator is desirably secured to the external surface of the container in the vicinity of the first edge of the indicator.”), 8:18-19 (“The indicator is preferably attached to an eternal

surface of the ferrule or the container, more preferably the container.”), 9:19-20 (“an annular mechanical dose indicator arranged to be mounted circumferentially about the dispensing –canister and secured to an external surface of the dispensing canister”), 9:29-30 (“said annular mechanical dose indicator being arranged to be mounted circumferentially about the dispensing –canister and secured to an external surface of the dispensing canister”), 15:11-14 (“The indicator (50) is mounted circumferentially about the dispensing canister, such that the first edge (51) faces towards the closed end (2) of the container and the second edge (52) faces towards the outlet of the dispensing canister, so that at least the outlet member (5) of the canister extends beyond the second edge (52) of the indicator.”), 15:24-28 (“As can be recognized in the preferred embodiment depicted in Fig. 4, the indicator (50) is secured directly to an external surface of the dispensing-canister (10), preferably an external surface of the container (1) (in particular an external surface of the side-wall (9) of the container), more preferably an external surface of the container in the vicinity of the first edge (51) of the indicator.”). In part because this claim requirement of “operation by movement of the medicament canister” is not met, the ’514 Publication fails to disclose this limitation of Asserted Claim 1 under either Plaintiffs’ or Defendants’ construction of “actuation member.”

250. As I stated above, I understand that the parties dispute the construction of “actuation member.” I have reproduced the parties’ competing constructions below.

<u>No.</u>	<u>Term</u>	<u>Plaintiffs’ Construction</u>	<u>Defendants’ Construction</u>
1	“actuation member” ’289 Patent, claims 1, 3 ’587 Patent, claims 1, 3, 11, 12, 13 ’156 patent, claims 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a component of the dose counter’s actuator that	“pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count”

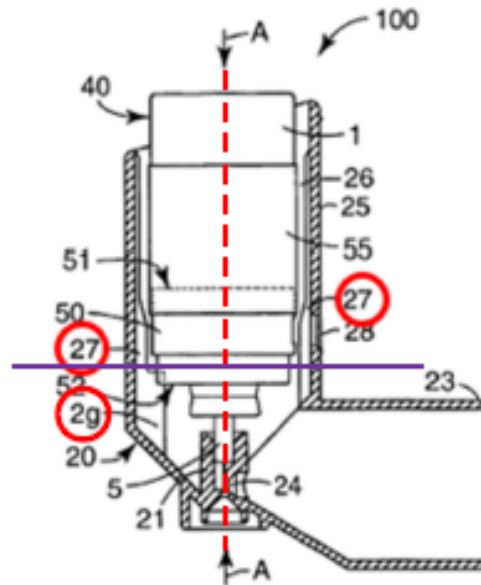
<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
		transmits motion from the canister to the actuator”	

251. Under Teva’s construction of “actuation member,” the ’514 Publication fails to disclose an “actuation member” of Asserted Claim 1 for additional reasons. First, neither actuation pin 29 or 2g or 23 nor receiving surface 36 or 96 is (alone or in combination) “a component of the dose counter’s actuator.” I understand the parties agree that an “actuator” is “[a] structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component.” *See* Joint Claim Construction Chart 4. Certainly, actuation pin 29 or 2g or is not “a structure *within* the dose counter” because it is located outside the dose indicator of the ’514 Publication. To the extent Mr. Anderson suggests that the actuation member is actuation pin 29 or 2g in combination with receiving surface 36 or 96, that combination is neither “a component” nor “a structure” nor “within” the dose counter. In addition, neither actuation pin 29 or 2g nor receiving surface 36 or 96 (separately or in combination) is “moved” by the canister. Actuation pin 29 or 2g does not move at all (and thus is also not “moveable relative to other components of the dose counter”), and neither actuation pin 29 or 2g nor receiving surface 36 or 96 interacts with the canister whatsoever. Actuation pin 29 or 2g does not ever contact the canister, it contacts receiving surface 36 or 96. And receiving surface 36 or 96, by contrast, is affixed inside of the dose indicator, the outer body of which is in turn affixed to the canister. Indeed, the ’514 Publication does not disclose any feature of the dose counter that “can be moved by the canister” and “is moveable relative to other components of the dose counter,” let alone a feature with those characteristics in which the “actuation member” is a component.

252. Under Defendants' construction, the '514 Publication does not disclose an actuation member for additional reasons. Neither actuation pin 29 or 2g nor receiving surface 36 or 96 (separately or in combination) is "arranged to engage with a medicament canister." As I stated, actuation pin 29 or 2g does not ever contact the canister, it contacts receiving surface 36 or 96. And receiving surface 36 or 96, by contrast, is affixed inside of the dose indicator, the outer body of which is in turn affixed to the canister. In addition, receiving surface 36 or 96 is not a "pin" nor is a structure that is a combination of elements 36 or 96 and 29 or 2g.

253. Because the '514 Publication does not disclose an actuation member within the meaning of Asserted Claim 1, it cannot disclose the claimed configuration of the inhaler in which an inner wall canister support formation and center of the central outlet port are in a common plane with the actuation member.

254. Mr. Anderson suggests that the '514 Publication discloses an inner wall canister support formation and central outlet port that lie on a common plane with the central outlet port, where that common plane is shown by a purple line he has added to Figure 8a. Anderson Opening Rep. ¶ 143. I have reproduced Mr. Anderson's annotated version of Figure 8a below.

**Fig. 8a**

255. I do not understand what common plane Mr. Anderson is identifying, and he does not explain it. To the extent Mr. Anderson suggests the common plane extends out from the page toward the reader, this plane is not “coincident with longitudinal axis X,” as Asserted Claim 1 requires.

256. Moreover, Mr. Anderson has not identified a common plane that passes through all of the inner wall cannister support formation, actuation pin 2g or 29, and inclined receiving surface 36 or 96. Inclined receiving surface 36 or 96 is simply not shown in Figure 8a and thus Figure 8a cannot be annotated to depict a common plane including it. Even if I were to accept Mr. Anderson’s annotated version of Figure 9c (and the POSA would not have done so), no plane that connects the inclined receiving surface to the actuation pin (a feature Cipla argues is coextensive with the inner wall canister support formation) also intersects the center of the central outlet port. Certainly, Mr. Anderson does not show such a plane.

257. Mr. Anderson states in paragraph 144 of his opinion that “driving member 90 or

the receiving surface 96 of the driving member 90 may also be considered actuation members.” I disagree. I have addressed “receiving surface 96” in detail above. Driving member 90 is likewise not an actuation member. Driving member 90 is located entirely within the dose indicator, and therefore does not have “at least a portion thereof located in the canister housing” as Asserted Claim 1 requires. ’514 Publication, Abstract, 4:18, 6:11-14, 26:5-7 (“[T]he counter-ring and driving member are located or mounted *within the housing of the indicator*.” (emphasis added)). Likewise, driving member 90 never touches the medication canister and so is not “operated by movement of the medicament canister.” Indeed, structure 96 or 36 is mounted to the dose indicator’s housing, which is in turn mounted to the medication canister, and therefore that structure *cannot* move relative to the medication canister. No component of the dose indicator of the ’514 Publication can be “operated by movement of the medicament canister,” as the claim requires, because the dose indicator is affixed to the canister. *See, e.g.*, ’514 Publication, 4:22-23 (“wherein said indicator is arranged to be circumferentially mountable about the dispensing canister”), 6:4-8 (“Annular dose indicators according to the invention are advantageous in that the indicator can be manufactured independent of the dispensing-canister and the adaptor to provide a self-contained assembly. They can be easily mounted around the dispensing canister by sliding the indicator over the outlet- or container-end of the dispensing canister, as the case may be.”), 7:16-24 (“Furthermore dose indicators, in particular the housing, can be advantageously secured to an external surface of the dispensing canister, preferably to an external surface of the container or, if applicable the ferrule of the dispensing canister, to provide a self-contained canister/indicator assembly. The provision of a dispensing-canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure means) and above the outlet means of the canister is

particularly advantageous, because such an assembly is desirably robust.”), 8:6-14 (“an annular mechanical dose indicator mounted circumferentially about the dispensing-canister and secured to an external surface of the dispensing canister. . . . Preferably the indicator is secured to an external surface of the container. In particular the indicator is desirably secured to the external surface of the container in the vicinity of the first edge of the indicator.”), 8:18-19 (“The indicator is preferably attached to an external surface of the ferrule or the container, more preferably the container.”); 9:19-20 (“an annular mechanical dose indicator arranged to be mounted circumferentially about the dispensing –canister and secured to an external surface of the dispensing canister”), 9:29-30 (“said annular mechanical dose indicator being arranged to be mounted circumferentially about the dispensing –canister and secured to an external surface of the dispensing canister”), 15:11-14 (“The indicator (50) is mounted circumferentially about the dispensing canister, such that the first edge (51) faces towards the closed end (2) of the container and the second edge (52) faces towards the outlet of the dispensing canister, so that at least the outlet member (5) of the canister extends beyond the second edge (52) of the indicator.”), 15:24-28 (“As can be recognized in the preferred embodiment depicted in Fig. 4, the indicator (50) is secured directly to an external surface of the dispensing-canister (10), preferably an external surface of the container (1) (in particular an external surface of the side-wall (9) of the container), more preferably an external surface of the container in the vicinity of the first edge (51) of the indicator.”).

258. In addition, under Teva’s construction, driving member 90 is an actuation member because it is not “moved” by the canister. Driving member 90 does not ever contact the canister—it is affixed inside of the dose indicator, the outer body of which is in turn affixed to the canister. Under Defendants’ construction, driving member 90 is not an actuation member because it is not

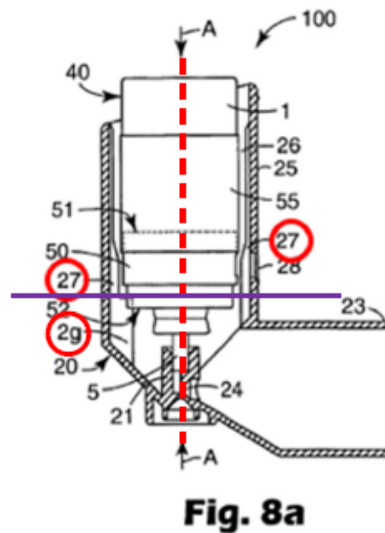
a pin nor is it “arranged to engage” with the canister. As I have explained, it does not ever contact the canister. Mr. Anderson states that “At least a portion of this driving member 90 and the receiving surface 96, which can act to actuate the dose counter when depressed by the canister, lie in the same plane as actuation pin 29. Therefore, that portion of the driving member 90 or the receiving surface 96 of the driving member 90 that lies in the same plane as actuation pin 29 can be considered the actuation member as recited in Claim 1 of the ’289 Patent.” Anderson Opening Rep. ¶ 145. I disagree. For all the reasons I explained above, neither driving member 90 nor receiving surface 96 is an actuation member, and those reasons apply with equal force to demonstrate that no smaller portion of either of these features is an actuation member.

259. As I stated above, I understand that the parties dispute the construction of the Common Plane Limitation. I have reproduced the parties’ competing constructions below.

<u>No.</u>	<u>Term</u>	<u>Plaintiffs’ Construction</u>	<u>Defendants’ Construction</u>
2	<p>“[lying or lie] in a common plane coincident with the longitudinal axis X”</p> <p>’289 Patent, claim 1</p> <p>’587 Patent, claims 1, 12, 21, 22</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.</p>	<p>“aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member”</p>

In connection with Defendants’ construction, Mr. Anderson states that “As shown in Figure 8a above, the ’514 Publication discloses a support formation (21) located directly adjacent to the actuation pin (2g).” Anderson Opening Rep. ¶ 145. I have reproduced Figure 8a from paragraph 143 of Mr. Anderson’s report below—as is clear, element 21 is the valve stem block, which the

'514 Publication refers to as “support block (21).” '514 Publication, 28:23-27 (“The support-portion (220), which comprises a patient port, in particular a mouthpiece (23) and a support block (21) having a socket (22) adapted to receive the outlet member of the dispensing-canister (10) and an orifice (24) having open communication with the socket and mouthpiece, is reversibly attachable and detachable.”).



As shown in Figure 8a, structure 21 emerges from the base of the inhaler. It cannot be the “inner wall canister support formation” that is “directly adjacent” to the “actuation member” because it is not an inner wall canister support formation. I understand the parties have agreed that “inner wall” means “an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body.” See Joint Claim Construction Chart 5. Element 21 in Figure 8a extends from the “bottom surface, or floor, of the inhaler body” rather than an inner wall of the canister body and is therefore not an “*inner wall* canister support formation.” Furthermore, the valve stem block located directly in the center of the inhaler’s base, and therefore is not adjacent to the actuation pin (2g), which is attached to the inner wall. Accordingly, under

Defendants' construction, the '514 Publication fails to disclose the Common Plane Limitation for this additional reason.

b) Claim 4

260. Asserted Claim 4 of the '289 Patent depends from Asserted Claim 1 of the '289 Patent and recites: "The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the '514 Publication does not disclose an "inhaler as claimed in claim 1." *See supra* Section VI.A.1.b.1)a). Thus, the '514 Publication does not anticipate this claim.

261. In addition, Mr. Anderson states that the inner wall canister support formation that "comprises a support rail which extends longitudinally along an inside surface of the main body" is element 27 of Figure 2a. Anderson Opening Rep. ¶ 147. Figure 2a of the '514 Publication does not contain any structure that Mr. Anderson has alleged is an actuation member. Thus, there is no basis to conclude that rib 27 lies in a common plane with any feature Mr. Anderson has identified as an actuation member (nor is directly adjacent to such a feature, as Defendants' construction would require). In addition, Mr. Anderson's combination of Figure 2a with Figures 8a and 9c (on which he relies for claim 1) mixes and matches embodiments of the '514 Publication. Figure 2 shows "vertical cross-sectional views of two exemplary, conventional adaptors; an adaptor for a press-and-breathe type inhaler and an adaptor for a breath- actuated inhaler." '514 Publication, 11:19-21. These adaptors are not the same as those configured for use with the annular dose indicator of the '514 Publication as depicted in, for example, Figure 8. *See, e.g.*, '514 Publication, 25:4-22. Mr. Anderson does not identify any disclosure in Figures 8a and 9c that satisfies this additional limitation of this dependent claim.

262. In addition, element 21 of Figure 8a, which, with respect to Asserted Claim 1, Mr.

Anderson asserts is the “inner wall canister support formation” that is “directly adjacent” to the actuation member under Defendants’ construction of the Common Plane Limitation does not extend longitudinally along an inside surface of the main body.

c) Claim 5

263. Asserted Claim 5 of the ’289 Patent depends from Asserted Claim 4 of the ’289 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.” In my opinion, at a minimum, the ’514 Publication does not disclose an “inhaler as claimed in claim 4.” *See supra* Section VI.A.1.b.1)b). Thus, the ’514 Publication does not anticipate this claim.

264. Furthermore, Mr. Anderson states that the inner wall canister support formation that “includes a step formed thereon” is element 27 of Figure 2a. Anderson Opening Rep. ¶ 149. Figure 2a of the ’514 Publication does not contain any structure that Mr. Anderson has alleged is an actuation member. Thus, there is no basis to conclude that rib 27 lies in a common plane with any feature Mr. Anderson has identified as an actuation member (nor is directly adjacent to such a feature, as Defendants’ construction would require). In addition, Mr. Anderson’s combination of Figure 2a with Figures 8a and 9c (on which he relies for claim 1) mixes and matches embodiments of the ’514 Publication. Figure 2 shows “vertical cross-sectional views of two exemplary, conventional adaptors; an adaptor for a press-and-breathe type inhaler and an adaptor for a breath-actuated inhaler.” ’514 Publication, 11:19-21. These adaptors are not the same as those configured for use with the annular dose indicator of the ’514 Publication as depicted in, for example, Figure 8. *See, e.g.*, ’514 Publication, 25:4-22. Mr. Anderson does not identify any disclosure in Figures 8a and 9c that satisfies this additional limitation of this dependent claim.

265. In addition, Mr. Anderson does not identify a “step formed thereon” in element 21 of Figure 8a, which, with respect to Asserted Claim 1, Mr. Anderson asserts is the “inner wall

canister support formation” that is “directly adjacent” to the actuation member under Defendants’ construction of the Common Plane Limitation.

d) Claim 6

266. Asserted Claim 6 of the ’289 Patent depends from Asserted Claim 4 of the ’289 Patent and recites: “The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the ’514 Publication does not disclose an “inhaler as claimed in claim 4.” *See supra* Section VI.A.1.b.1)b). Thus, the ’514 Publication does not anticipate this claim.

267. Furthermore, Mr. Anderson states that Figure 2a of the ’514 Publication discloses a “plurality of support rails each of which extends longitudinally along an inside surface of the main body.” Anderson Opening Rep. ¶ 151. The inner wall canister support formation that “includes a step formed thereon” is element 27 of Figure 2a. Figure 2a of the ’514 Publication does not contain any structure that Mr. Anderson has alleged is an actuation member. Thus, there is no basis to conclude that any of the support rails depicted therein lies in a common plane with any feature Mr. Anderson has identified as an actuation member (nor is directly adjacent to such a feature, as Defendants’ construction would require). In addition, Mr. Anderson’s combination of Figure 2a with Figures 8a and 9c (on which he relies for claim 1) mixes and matches embodiments of the ’514 Publication. Figure 2 shows “vertical cross-sectional views of two exemplary, conventional adaptors; an adaptor for a press-and-breathe type inhaler and an adaptor for a breath actuated inhaler.” ’514 Publication, 11:19-21. These adaptors are not the same as those configured for use with the annular dose indicator of the ’514 Publication as depicted in, for example, Figure 8. *See, e.g.*, ’514 Publication, 25:4-22. Mr. Anderson does not identify any disclosure in Figures 8a and 9c that satisfies this additional limitation of this dependent claim.

268. In addition, element 21 of Figure 8a, which, with respect to Asserted Claim 1, Mr.

Anderson asserts is the “inner wall canister support formation” that is “directly adjacent” to the actuation member under Defendants’ construction of the Common Plane Limitation does not extend longitudinally along an inside surface of the main body.

e) Claim 7

269. Asserted Claim 7 of the ’289 Patent depends from Asserted Claim 6 of the ’289 Patent and recites: “The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other.” In my opinion, at a minimum, the ’514 Publication does not disclose an “inhaler as claimed in claim 6.” *See supra* Section VI.A.1.b.1)d). Thus, the ’514 Publication does not anticipate this claim.

270. Furthermore, Mr. Anderson states that Figure 2a of the ’514 Publication discloses that “two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other.” Anderson Opening Rep. ¶ 152. Figure 2a of the ’514 Publication does not contain any structure that Mr. Anderson has alleged is an actuation member. Thus, there is no basis to conclude that any of the support rails depicted therein lies in a common plane with any feature Mr. Anderson has identified as an actuation member (nor is directly adjacent to such a feature, as Defendants’ construction would require). In addition, Mr. Anderson’s combination of Figure 2a with Figures 8a and 9c (on which he relies for claim 1) mixes and matches embodiments of the ’514 Publication. Figure 2 shows “vertical cross-sectional views of two exemplary, conventional adaptors; an adaptor for a press-and-breathe type inhaler and an adaptor for a breath actuated inhaler.” ’514 Publication, 11:19-21. These adaptors are not the same as those configured for use with the annular dose indicator of the ’514 Publication as depicted in, for example, Figure 8. *See, e.g.*, ’514 Publication, 25:4-22. Mr. Anderson does not identify any disclosure in Figures 8a and 9c that satisfies this additional limitation of this dependent claim. Mr. Anderson does not identify any disclosure in Figures 8a and 9c that satisfies this additional

limitation of this dependent claim.

f) Claim 8

271. Asserted Claim 8 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." In my opinion, at a minimum, the '514 Publication does not disclose an "inhaler as claimed in claim 4." *See supra* Section VI.A.1.b.1)b). Thus, the '514 Publication does not anticipate this claim.

272. Furthermore, Mr. Anderson states that Figure 2a of the '514 Publication discloses support rails with "two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." Anderson Opening Rep. ¶ 154. Figure 2a of the '514 Publication does not contain any structure that Mr. Anderson has alleged is an actuation member. Thus, there is no basis to conclude that any of the support rails depicted therein lies in a common plane with any feature Mr. Anderson has identified as an actuation member (nor is directly adjacent to such a feature, as Defendants' construction would require). In addition, Mr. Anderson's combination of Figure 2a with Figures 8a and 9c (on which he relies for claim 1) mixes and matches embodiments of the '514 Publication. Figure 2 shows "vertical cross-sectional views of two exemplary, conventional adaptors; an adaptor for a press-and-breathe type inhaler and an adaptor for a breath actuated inhaler." '514 Publication, 11:19-21. These adaptors are not the same as those configured for use with the annular dose indicator of the '514 Publication as depicted in, for example, Figure 8. *See, e.g.*, '514 Publication, 25:4-22. Mr. Anderson does not identify any disclosure in Figures 8a and 9c that satisfies this additional limitation of this dependent claim.

273. In addition, Mr. Anderson does not identify a "two steps formed thereon" in element 21 of Figure 8a, which, with respect to Asserted Claim 1, Mr. Anderson asserts is the

“inner wall canister support formation” that is “directly adjacent” to the actuation member under Defendants’ construction of the Common Plane Limitation.

2) The ’587 Patent

274. Mr. Anderson asserts that the ’514 Publication anticipates Asserted Claims 1, 4-8, 11 and 12 of the ’587 Patent. I disagree, and I incorporate by reference my analysis of the ’514 Publication in Section IV.C as though fully set forth herein. I have not reproduced that section here solely for the sake of brevity.

a) Claim 1

275. As I explain above, Asserted Claim 1 of the ’587 Patent is materially identical to Asserted Claim 1 of the ’289 Patent, except that Asserted Claim 1 of the ’587 Patent adds the additional that “the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

276. Because Asserted Claim 1 of the ’587 Patent contains every limitation of Asserted Claim 1 of the ’289 Patent, I conclude for the reasons I described above that the ’514 Publication does not disclose every limitation of Asserted Claim 1 of the ’587 Patent. I incorporate all of those reasons set forth in Section VI.A.1.b.1)a) above into this Section, as if set forth fully herein. I have not repeated them solely for the sake of brevity.

277. Furthermore, the ’514 Publication fails to anticipate Asserted Claim 1 of the ’587 Patent because the ’514 Publication does not disclose “that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

278. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the ’514 Publication because the ’514 Publication “discloses every

structural element” of the claim and these structure elements necessarily “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” *See* Anderson Opening Rep. ¶ 158.

279. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler) that the Asserted Claims of the ’289 Patent do not require, and obtaining this result imposes structural limitations on the configuration of the canister housing (including inner wall canister support formations) and dose counter.

280. Regardless, I disagree that the ’514 Publication “discloses every structural element” of the claim—as I described above with respect to Asserted Claim 1 of the ’289 Patent, the ’514 Publication fails to disclose several limitations of Asserted Claim 1.

281. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter—even were it disclosed in the ’514 Publication, and it is not—is sufficient to establish that the arrangement necessarily will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation, by analyzing the effect of removing the inner wall canister support formation from Defendants’ ANDA Products. The ’514 Publication does not indicate its inner wall canister support formations are configured to “protect against unwanted actuation of the dose counter by

reducing rocking of the medicament canister relative to the main body of the inhaler,” nor does it provide the details regarding its structure that the POSA would need to conduct the analysis necessary to determine whether the devices disclosed in the ’514 Publication necessarily satisfy this limitation.

282. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



283. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

b) Claim 4

284. Asserted Claim 4 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1, first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the '514 Publication does not disclose an "inhaler as claimed in claim 1." *See supra* VI.A.1.b.2)a). Thus, the '514 Publication does not anticipate this claim. I incorporate all of those reasons set forth in Section VI.A.1.b.2)a) above into this Section, as if set forth fully herein. I have not repeated them solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 4 of the '289 Patent, which contains the same additional limitation as Asserted Claim 4 of the '587 Patent. *See supra* Section VI.A.1.b.1)b).

c) Claim 5

285. Asserted Claim 5 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the '514 Publication does not disclose an "inhaler as claimed in claim 4," because it does not disclose the limitations of Asserted Claim 1 or the additional limitation of Asserted Claim 4. *See supra* Section VI.A.1.b.2)b). I incorporate all of those reasons set forth in Section VI.A.1.b.2)b) above into this Section, as if set forth fully herein. Thus, the '514 Publication does not anticipate this claim. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 5 of the '289 Patent, which contains the same additional limitation as Asserted Claim 5 of the '587 Patent. *See supra* Section VI.A.1.b.1)c).

d) Claim 6

286. Asserted Claim 6 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4 further comprising a plurality of support

rails each of which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the ’514 Publication does not disclose an “inhaler as claimed in claim 4.” *See supra* Section VI.A.1.b.2)b). I incorporate all of those reasons set forth in Section VI.A.1.b.2)b) above into this Section, as if set forth fully herein. Thus, the ’514 Publication does not anticipate this claim. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 6 of the ’587 Patent. *See supra* Section VI.A.1.b.1)d).

e) Claim 7

287. Asserted Claim 7 of the ’587 Patent depends from Asserted Claim 6 of the ’587 Patent and recites: “The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other.” In my opinion, at a minimum, the ’514 Publication does not disclose an “inhaler as claimed in claim 6.” *See supra* Section VI.A.1.b.2)d). I incorporate all of those reasons set forth in Section VI.A.1.b.2)b) above into this Section, as if set forth fully herein. Thus, the ’514 Publication does not anticipate this claim. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 7 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 7 of the ’587 Patent. *See supra* Section VI.A.1.b.1)e).

f) Claim 8

288. Asserted Claim 8 of the ’587 Patent depends from Asserted Claim 4 of the ’587 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the ’514 Publication does not disclose an “inhaler as claimed in claim 4.” *See supra* Section VI.A.1.b.2)b). I incorporate all of those reasons set forth in Section VI.A.1.b.2)b) above into this Section, as if set forth fully herein. Thus, the ’514 Publication does

not anticipate this claim. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 8 of the '289 Patent, which contains the same additional limitation as Asserted Claim 8 of the '587 Patent. *See supra* Section VI.A.1.b.1)f).

g) Claim 11

289. Asserted Claim 11 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: “The inhaler as claimed in claim 1 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.” In my opinion, at a minimum, the '514 Publication does not disclose an “inhaler as claimed in claim 1.” *See supra* Section VI.A.1.b.2)a). Thus, the '514 Publication does not anticipate this claim.

290. Furthermore, to the extent the Court adopts Defendants' construction of the Common Plane Limitation, the '514 Publication does not disclose one, let alone two inner wall canister support formations that are “directly adjacent” to the actuation member. As I described above, Mr. Anderson identifies “support formation (21)” in Figure 8c and asserts that it is “directly adjacent” to “actuation pin (2g).” As I explain above, not only do I disagree that “actuation pin (2g)” is an “actuation member” within the meaning of Asserted Claim 1, I also disagree that “support formation (21)” is an “inner wall canister support formation” and that “support formation (21)” is directly adjacent to “actuation pin (2g).” Furthermore, Mr. Anderson does not identify any, second “inner wall canister support formation” as being directly adjacent to “actuation pin (2g).”

h) Claim 12

291. Asserted Claim 12 of the '587 Patent is materially identical to Asserted Claim 1 of the '289 Patent, except that Asserted Claim 12 of the '587 Patent adds the additional limitation

“such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

292. Because Asserted Claim 12 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that the '514 Publication does not disclose every limitation of Asserted Claim 12 of the '587 Patent. *See supra* Section VI.A.1.b.1)a).

293. Furthermore, the '514 Publication fails to anticipate Asserted Claim 12 of the '587 Patent because the '514 Publication does not disclose “that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

294. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '514 Publication because the '514 Publication “discloses every structural element” of the claim and these structure elements necessarily protect against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. Anderson Opening Rep. ¶ 158.

295. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member) that the '289 Patent does not require.

296. Regardless, I disagree that the '514 Publication “discloses every structural element” of the claim—as I described above, the 406 Publication fails to disclose several limitations of Asserted Claim 1 of the '289 Patent and Asserted Claim 1 of the '587 Patent.

297. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose

counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation.

298. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



299. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly

of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

300. Mr. Anderson does not separately address Asserted Claim 12 in his analysis, instead conflating its final limitation with the final limitation of Asserted Claim 1. That is incorrect. Reducing rocking of the canister with respect to the main body of the inhaler is not the same as reducing rocking of the canister towards or away from the actuation member. To the contrary, the POSA would have understood that certain support rail configurations could achieve the former but not the latter. Nothing in the '514 Publication discloses an inner wall canister support formation that prevents rocking of the canister towards or away from the actuation member.

* * *

301. I note that the '514 Publication was before the examiner during prosecution of the '289 and '587 Patents. *See, e.g.,* '289 Patent, Foreign Patent Documents; '587 Patent, Foreign Patent Documents. I have conducted an independent analysis of the '514 Publication, and in my opinion, the '514 Publication does not anticipate the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the '514 Publication does not anticipate those claims.

2. Mr. Anderson's Obviousness Opinions Are Incorrect

302. Mr. Anderson sets forth four distinct obviousness theories, namely that the Asserted Claims of the '289 and '587 Patents would have been obvious to the POSA (1) in light of the '406 Publication; (2) in light of the '514 Publication in combination with the '406 Publication, (3) in light of the '021 Publication, and (4) in light of the '514 Publication in combination with the '021 Publication. I disagree with each theory. I do not agree with Mr. Anderson that the POSA would have had reason to select the dose counter of either the '406 Publication or the '021 publication

for modification, nor that the POSA would have had reason to modify either of those dose counters in a manner that led to the claimed invention. Mr. Anderson's assumption to the contrary is premised on hindsight alone—he offers no reason for this selection, and as I explain below, there are many reasons why the POSA would not have selected the dose counters of the '406 and '021 Publications. I also disagree that the POSA would have had reason to combine the dose counters of either the '406 Publication or the '021 Publication with the canister housing of the '514 Publication, nor do I agree that such a combination would have led the POSA to the claimed invention. Again, Mr. Anderson's analysis to the contrary is premised on hindsight. Mr. Anderson ignores the manner in which the canister housing of the '514 Publication was adapted to suit the annular dose counter that Publication disclosed, and wrongly assumes that such a canister housing would be operable with the dose counters of the '406 and '021 publications. He also wrongly assumes that the POSA who chose to combine the '514 Publication with the dose counter of either the '406 or '021 Publications would have aligned the support rails of the canister housing of the '514 Publication in a manner that satisfied the Common Plane Limitation, but provides no support whatsoever for these assertions. These unsupported arguments demonstrate that Mr. Anderson's obviousness opinion proceeded by beginning with the claimed inventions, and working backwards to piece them together. I am informed that such an approach is not permissible under the law.

303. My analysis instead reflects what the POSA would have had reason to do as of the priority date based on the prior art. In particular, the POSA would have faced numerous decision points and design obstacles that consistently led them away from the claimed invention rather than toward it. For example, as of the priority date, the POSA seeking to satisfy FDA's 2003 Guidance by adding a dose tracking feature to an MDI would face a choice between developing a dose *indicator* or an inhaler or a dose *counter*. See FDA Guidance at TEVAQVAR-00032576; Stein at

334. The POSA without hindsight knowledge of Teva's invention would have selected a dose indicator rather than a dose counter. *See, e.g.*, Stuart, at 43, TEVADOC-00000534. Had the POSA selected a dose indicator instead of a dose counter, the POSA would not have arrived at the inventions claimed in the Asserted Claims of the '289 and '587 Patents. I do not understand Defendants or their expert Mr. Anderson to assert otherwise.

304. Fundamentally, the POSA would have appreciated that developing a dose indicator or dose counter was a challenging undertaking. Stein at 334; Stuart at 40-43. The FDA's 2003 Guidance explicitly contemplates that less-precise dose counters would have satisfied its recommendations, FDA Guidance 2003, TEVAQVAR-00032577-78, and the POSA would have understood dose indicators to pose less of a design challenge, particularly where high numbers of doses needed to be counted. In particular, dose indicators can be smaller than dose counters because they need not have a display capable of displaying hundreds of numbers—indeed, “an indicator is often the only choice when it is difficult to fit a numerical display that can count down in individual increments from 200 doses within the space limitations of a conventional MDI actuator.” Stuart, at 43, TEVADOC-00000534. Dose indicators can use larger font and can be manufactured at lower costs. *See* Stuart, at 41, TEVADOC-00000532. The risk of miscounting is also lessened when an indicator is used, since the patient cannot rely on the indicator to determine precisely how many doses remain, but only when the device is approaching the end of its life. Under those circumstances, the need to avoid sporadic over- or under-counting events is not as critical. In my opinion, had the POSA elected to develop a dose tracking system for integration into an MDI product, the POSA would have chosen to develop a dose indicator. And as my analysis of the Alleged Prior Art reflects, many of the references on which Mr. Anderson relies in fact disclose dose indicators—either in addition to or in place of dose counters. *See supra*

Section IV. I incorporate by reference my analysis of each prior art reference in Section IV as though fully set forth herein, but I do not repeat that analysis here solely for the sake of brevity. As a result, the POSA thus would have been led away from the claimed inventions, which require dose counters.

305. Even assuming, contrary to my opinion, that the POSA had chosen to develop a dose counter rather than a dose indicator, the POSA would have faced a choice about where to locate the dose counter relative to the canister housing and medication canister. In my opinion, the POSA would not have chosen to locate the dose counter below or even partially below the medication canister, but rather would have utilized a device that was located, for example, on top of the canister housing, because such a device “can be added to a design without affecting existing components or pre-existing drug delivery.” Stuart, at 41, TEVADOC-00000532. Put another way, artisans in the field had developed reliable inhalers *without* dose counters or dose indicators before the priority date, and these devices combined features of ease-of use, patient familiarity, reliability, robustness, and ease of manufacture, among others. The POSA would not have desired to alter these tried and tested devices in any way that might interfere with these helpful characteristics. Using a dose counter that is thus separated from the existing components of the inhaler that effectuate reliably the actuation of the device upon a patient’s input of force, would have been considered a far simpler, easier to manufacture, less costly, and more reliable approach. By pursuing a dose counter below or partially below the medicament canister, the POSA would have risked modifying unduly the design of the existing system, adding both significant complexity and the potential for failure. For example, locating the dose counter partially or fully below the canister would have required adapting the inhaler housing, which would have required testing, not to mention creating new molds to permit manufacture. Engineers in this field value simplicity, and

placing the dose counter partially or fully below the canister would have been considered a complicated, undesirable and unsuitable choice. And as my analysis of the Alleged Prior Art reflects, many of the references on which Mr. Anderson relies in fact disclose dose counters or dose indicators so positioned. *See supra* Section IV. I incorporate by reference my analysis of each prior art reference in Section IV as though fully set forth herein, but I do not repeat that analysis here solely for the sake of brevity.

306. Simply put, the POSA would have had reason to place the dose counter on top of the canister because the POSA would have understood that this approach was simpler and therefore more likely to be successful. As the POSA would have understood, the need to manufacture inhalation products on a large scale and at limited required simplicity in design. By adding a counter to the top of the canister, the POSA would have overcome one of the principle challenges of dose counting for MDIs—limited space. The very small amount of travel available to count if the dose counter were located fully or partially underneath the canister requires development of an exceptionally small dose counter, and would have provided little leeway to accommodate the manufacturing variability that the POSA would have expected to be associated with the bulk manufacture of dose counter components. *See, e.g.,* Stuart 2013, at 42, TEVADOC-00000533. As the prior art recognized, locating the dose counter “substantially beneath the canister” “can be disadvantageous in that modification of the adaptor geometry, such as greater dimensions, in the critical region where atomization takes place is generally required.” ’514 Publication, 3:5-10. The POSA would have understood that altering the adaptor geometry would lead to unwarranted complexity in the form of testing and new manufacturing practices. As my analysis of the Alleged Prior Art reflects, the prior art taught that the POSA would have sought to avoid such testing and expense. *See supra* Section IV. I incorporate by reference my analysis of each prior art reference

in Section IV as though fully set forth herein, but I do not repeat that analysis here solely for the sake of brevity.

307. In addition, placing the counter above the canister rather than below it means that operation of the dose counter does not depend on the particular valve selected for use in the system. As the POSA would have understood, the distance that the canister travels before firing (as well as its total travel distance) is determined by the valve selected—different valves travel different distances before firing, and even the same valve can experience changes in travel distances over time. If the dose counter were situated beneath the canister, the dose counter’s function would need to account for these many variables, and be tailored to the precise valve selected for use in the inhaler. By locating the dose counter on top of the canister, the POSA avoids all of these design challenges. These considerations would have given the POSA reason to avoid a counter actuated beneath the canister, and instead would have given the POSA reason to pursue a top-mounted counter. The POSA would thus have been led away from the claimed invention. As my analysis of the Alleged Prior Art reflects, the prior art taught that the POSA would have valued simplicity in design and recognized the need to adapt a dose counter located below or partially below the canister to the particular canister and valve chosen. *See supra* Section IV. I incorporate by reference my analysis of each prior art reference in Section IV as though fully set forth herein, but I do not repeat that analysis here solely for the sake of brevity. The teachings of those references are also consistent with my experience, and consistent with [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

308. The POSA would have selected a top-mounted dose counter, and would have been taught away from the location Teva ultimately used and claimed, for the additional reason that such a dose counter would have been less likely to alter air flow and drug performance. Indeed, the POSA would have been concerned that situating the dose counter below the medication canister would have had the potential to alter dose delivery. As the POSA would have understood, “[w]hen adding a dose counter to an existing product, all efforts must be made to ensure its presence does not affect the delivery of the drug.” Stuart 2013 at 42-43, TEVADOC-00000533-534. In particular, “airflow is a key consideration, as a change or restriction in airflow could lead to a significant change in the geometry of the spray plume and the efficiency of delivery to the lungs.” Stuart 2013, at 43, TEVADOC-00000534. The POSA would have chosen to avoid these design challenges by locating the dose counter on top of the medication canister. The POSA’s primary goal in incorporating a dose counter would have been to avoid any possible changes to the performance of device designs that had proven desirable and reliable for patients. Again, as my analysis of the Alleged Prior Art reflects, the prior art routinely taught concerns regarding a dose counter’s potential to disrupt airflow through the device. *See supra* Section IV. I incorporate by reference my analysis of each prior art reference in Section IV as though fully set forth herein,

but I do not repeat that analysis here solely for the sake of brevity. The POSA thus would have been led away from the claimed inventions. In such a case, the POSA would never even have encountered the problem solved by the claimed inventions, let alone arrived at the solution claimed, because the location of the dose counter would have been different than the location disclosed and claimed in the Asserted Patents.

309. In contrast, concerns regarding a top mounted or largely external dose counter would have been seen as minor in comparison to challenges faced if other design options were pursued. In particular, any concerns regarding increased height of the device and its exposure to the patient would have been considered minor and easily surmountable, these concerns readily compared with the technical challenge of engineering a reliable, robust, and accurate counter with an actuation member situated below the canister. *See* Stuart 2013, at 41, TEVADOC-00000532.

310. Even if, contrary to my opinion, the POSA had opted to pursue a dose counter and then, again contrary to my opinion, decided to locate the dose counter below the canister, the POSA would have made additional design choices that would have led the POSA away from the claimed inventions. In particular, the POSA would not have appreciated the advantage of controlling canister rocking in connection with the addition of a dose counter whose actuation member was located beneath the canister. Even had the POSA identified the advantage of addressing canister rocking when the dose counter is so located, the POSA would have sought to address it in alternative ways. For example, the POSA would have recognized that any deleterious movement of the canister precipitated by introduction of the dose counter could be avoided completely by affixing the dose counter to the medication canister. *See, e.g.,* '514 Publication. The POSA would have elected this approach, rather than the addition of one or more inner wall canister support formations, because the POSA would have expected such a solution to have a greater likelihood

of success.

311. Accordingly, the POSA would have faced numerous design decisions when seeking to add a dose tracking device to a metered dose inhaler, and in every instance would have made choices that led away from the claimed inventions. Without hindsight knowledge of the invention of the Asserted Patents (which I understand the POSA not to possess), the POSA would not have had reason to make any choice leading to the claimed invention, let alone the precise combination of choices that would have led the POSA to appreciate the problem identified and solved by the claimed inventions—and even had the POSA arrived at that juncture, the POSA would have elected to solve the problem in a manner other than the one claimed.

a. The '406 Publication Does Not Render Obvious the Asserted Claims of the '289 and '587 Patents

1) The '289 Patent

312. Mr. Anderson asserts that Asserted Claims 1-8 of the '289 Patent would have been obvious in light of the '406 Publication. I disagree, and I incorporate by reference my analysis of the '406 Publication in Section IV.A as though fully set forth herein, and I have not reproduced it here solely for the sake of brevity. I also incorporate as though set forth herein my analyses of the other references to which Mr. Anderson refers in his discussion of this obviousness theory—including my analyses of the '998 Patent in Section IV.E, the '008 Publication in Section IV.G, the '822 Patent in Section IV.H, the '668 Patent in Section IV.K, the '260 Publication in Section IV.L, Lewis in Section IV.W, and the '514 Publication in Section IV.C. Again, I do not reproduce those sections here solely for the sake of brevity.

a) Claim 1

313. Mr. Anderson opines that, to the extent the POSA would not have understood the '406 Publication to have disclosed an inner wall canister support formation, the POSA would have

been motivated to add the dose counter of the '406 Publication to a canister housing containing an inner wall canister support formation. I disagree that the '406 Publication discloses every limitation of Asserted Claim 1 of the '289 Patent, for the reasons I explain above, and I incorporate my analysis in Section VI.A.1.a.1)a) as though fully set forth herein. Furthermore, even if the POSA were to add inner wall canister support formations to the inhaler containing the dose counter of the '406 Publication, that would not have resulted in the claimed invention. In addition, I disagree that the POSA would have had reason to select any particular dose counter of the '406 Publication for modification, and I disagree that the POSA would have had reason to add that dose counter to an inhaler with inner wall canister support formations, all with a reasonable expectation of success. To that end, I incorporate my analysis in Sections VI.A.2 and V as though fully set forth herein, and I have not reproduced it here solely for the sake of brevity. The multiple decisions required to pursue such a combination were not supported by the prior art or understanding of the POSA; only hindsight knowledge of the invention would have justified that approach. In any event, the combination of the dose counter of the '406 Publication with an inhaler containing an inner wall canister support formation would not have led the POSA to the claimed inventions.

314. The POSA seeking to add a dose tracking device would not have selected any one of the five distinct dose counters disclosed in the '406 Publication for modification. To the contrary, for the reasons I explained above, the POSA would have pursued a dose indicator rather than a dose counter. *Supra* Sections VI.A.2 and Section V. And even had the POSA chosen to pursue a dose counter, the POSA would have pursued a dose counter located on top of the canister, not a dose counter located in whole or in part below the canister. *Supra* Sections VI.A.2 and Section V. The '406 Publication does not meet either of these criteria, and the POSA would not have selected it for further modification.

315. As I describe above, *Supra* Sections VI.A.2 and Section V, I also disagree with Mr. Anderson's assertion that "inner wall canister support formations" were "essentially ubiquitously used in MDIs" as of the priority date. To the contrary, many of the prior art references Mr. Anderson selected to support his opinions in this case describe inhalers without any reference to "inner wall canister support formations" or do not include such formations in embodiments with dose counters. *See, e.g.*, '406 Publication (depicting and describing inhalers without rails extending outwardly from the main body); '044 Publication (same); '817 Publication (same); '021 Publication (same); '191 Publication (Figures 31, 32, 70, 71, 73-76, 93, 136, depicting a canister housing without support rails); '552 Publication; '950 Publication; '627 Patent; GB '489; '159 Publication; '965 Publication; and '102 Publication (as I explained in detail above in Sections IV and V, which I incorporate by reference as though fully set forth herein). Other references described such ribs as optional. *See* '008 Publication, ¶ [0045] ("Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1."). Publication, 'Other references described such ribs as optional. *See* '008 Publication, ¶ [0045] ("Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1."); *see also* '514 Publication at 14:17-19; '822 Patent, 3:11-14. As those examples from Mr. Anderson's references alone reflect, inner wall canister support formations were anything but ubiquitous. Even today, inhalers are marketed without "inner wall canister support formations"—i.e., support rails. *See* Exhibit B.

316. Furthermore, the POSA would have resisted changing the canister housing associated with the dose counter of the '406 Publication, or adding any structure to the canister housing of a different inhaler. As the POSA would have understood, components of a system are

designed and disclosed to be used together, not to be mixed and matched from different systems or modified in ways that could alter critical features like the established airflow through the inhaler, which can affect product performance and/or require further regulatory approvals. *See, e.g.*, Stuart 2013 at 43, TEVADOC-00000534. Simply put, the POSA who chose to use the dose counter of the '406 Publication would have used the canister housing described for use with the dose counter of the '406 Publication, rather than—contrary to the very disclosure of the reference on which the POSA has chosen to rely—selecting some other canister housing or modifying the canister housing that the reference discloses. The POSA would have deemed Mr. Anderson's approach in this regard untenable and contrary to the disclosure and established, standard engineering principles applied as a matter of course in the field. *Supra* Sections VI.A.2 and Section V.

317. Even had the '406 Publication been silent regarding the potential for changing the canister housing, the POSA would have rejected such a change out of hand. But the '406 Publication expressly and repeatedly teaches the POSA not to do so. The '406 Publication emphasizes that the dose counters it discloses “require[s] minimal or no changes to the inside and/or outside profile and/or volume of the actuator to accommodate the counter.” *See, e.g.* '406 Publication, ¶¶ [0009] (“no or only minimal modification (in shape and/or size) of the housing” needed), [00105] (noting that “it is not necessary to change the external configuration of those actuator housings to accommodate the inventive dose counter”), [00124] (second embodiment), [00151] (third embodiment). In addition, the '406 Publication recognized the need for robust, reliable, precise, accurate, and readily manufacturable dose counters, but does not identify any problems with the performance of the dose counter it discloses. *See, e.g.*, '406 Publication, ¶¶ [0006], [0009]. In particular, the '406 Publication does not identify any issues with canister location, annular air flow, axial movement of the valve stem (which can result in unwanted gassing

of the canister), or tolerance control, which are the reasons for which Mr. Anderson suggest the POSA would have added inner wall canister support formations. The POSA would not rely on the '406 Publication (rather than all of the other publications that disclose alternative dose indicator and dose counter designs), only to disregard its teachings. On the basis of the prior art's disclosure, the POSA would not have had reason to alter the housing containing the dose counter of the '406 Publication, nor would the POSA reasonably have expected success in doing so.

318. Mr. Anderson suggests it would have been a departure from known practice, and less likely to result in a successful product, for the POSA *not* to have modified the '406 Publication by removing its dose counter from the housing disclosed in the '406 Publication and placing the dose counter of the '406 Publication into a different canister housing that contained support rails. I disagree. This opinion is contrary to the teaching of the '406 Publication itself, and would have been rejected by the POSA on that basis alone. In addition, as I explained above, successful products that do not include support rails are marketed today and many were marketed as of the priority date—for example, Atrovent®, Alupent®, Berodual®, Berotec®, Combivent®, and Budair® do not include support rails, and I have included images of each of these products in Exhibit B. And as I stated before, the POSA would have been concerned that any alterations to the inside of the canister housing, such as the addition of support rails, would have raised concerns regarding airflow disruption, alteration to product performance, or a need to seek new regulatory approvals. *See, e.g.*, Stuart 2013 at 43, TEVADOC-00000534. The POSA would have understood that the '406 Publication disclosed a housing that was suitable for use with its dose counter, not one that should be changed, at the risk of creating the foregoing problems. *Supra* Sections VI.A.2 and Section V.

319. Mr. Anderson also suggests that POSA would understand a “rib” was required in

the canister housing of the '406 Publication because the '406 Publication discloses “forward legs (378)” of its dose counter “mate with ‘interior surfaces of the actuator housing for the aerosol container 70” require the presence of a rib in the inner wall of the canister housing of the '406 Publication. Anderson Opening Rep. ¶ 171. As I explained above, I disagree with Mr. Anderson that the POSA would have interpreted the '406 Publication in that manner, or that the “forward legs (378)” in any way indicate the location of ribs extending inwardly from the inner wall of the canister housing. I incorporate by reference that analysis here.

320. Furthermore, even if the POSA had reason to remove the dose counter of the '406 Publication from the canister housing disclosed by the '406 Publication and place that dose counter into a canister housing containing “ribs” (and for the reasons I explain above, the POSA would not have done so), Mr. Anderson identifies no reason at all why the POSA would have had selected a canister housing whose ribs would have happened to lie a common plane with actuation member of the '406 Publication's dose counter. The only basis to have done so is hindsight. Mr. Anderson identifies no such basis in the prior art. To the contrary, Mr. Anderson asserts that the “'406 Publication discloses this requirement of claim 1.” Anderson Opening Rep. ¶ 171. For all the reasons I explained above, *supra* Section VI.A.1.a.1)a), Mr. Anderson is incorrect—nothing in the '406 Publication suggests the use of “inner wall canister support formations” at all, let alone that an inner wall canister support formation should be located in a common plane with the dose counter's actuation member and the central outlet port.

321. The non-obviousness of Asserted Claim 1 is further confirmed by the inventors' own experience. It was not until the inventors grappled with the results of integrating a dose counter into the canister housing, and had selected a dose counter with an actuation member extending into the canister housing operation by movement of the medicament canister, that the

inventors recognized the benefit of adjusting the location of the support rails to accommodate the dose counter. In particular, after adding such a dose counter to an existing canister housing, the inventors appreciated the benefits of “locat[ing the rails] to minimize the wobble of the canister above the counter plunger” and of adding “[a]dditional rails . . . to prevent excessive wobble of the canister within the body.” TEVAQVAR-00031848, at -854. The prior art disclosed none of this experience, knowledge, data, and modification.

322. Unlike the named inventors, the POSA seeking to modify the circular dose counter of the '406 Publication would not have recognized this problem (which, Mr. Anderson appears to acknowledge, was disclosed nowhere in the prior art) or had reason to solve it in the claimed manner with a reasonable expectation of success. The inventors of Asserted Claim 1, on the basis of their own non-public experimentation and expertise, could recognize the potential axes of canister wobble “above the counter plunger” given the “plunger’s” off-center point of contact with the canister within the canister housing. *See, e.g.*, TEVAQVAR-0003148, at -854. In contrast, the POSA seeking to integrate the circular dose counter of the '406 Publication into an existing canister housing would have expected that dose counter to contact the canister in a symmetrical fashion (otherwise the POSA certainly would not have so located a dose counter); thus, the POSA would not have had reason to alter the support rails in the canister housing to adjust canister wobble. Even would the POSA have recognized the benefit of altering the location of support rails in the canister housing in response to the dose counter’s introduction, the POSA would not have had a reasonable expectation that the claimed configuration of support rails would have been beneficial. In particular, the POSA would not have been able to identify or predict the principal axes of canister wobble (nor would the POSA have expected those axes to remain constant across all units), due to manufacturing tolerances for dose counter components and variation in patient

behavior.

b) Claim 2

323. Asserted Claim 2 depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.1)a). Thus, Asserted Claim 2 would not have been obvious to the POSA in light of the ’406 Publication.

c) Claim 3

324. Asserted Claim 3 of the ’289 Patent depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA as a result of the ’406 Publication. *See supra* Section VI.A.2.a.1)a). Thus, Asserted Claim 3 would not have been obvious to the POSA in light of the ’406 Publication.

d) Claim 4

325. Asserted Claim 4 of the ’289 Patent depends from Asserted Claim 1 of the ’289 Patent and recites: “The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.1)a). Thus, Asserted Claim 4 would not have been obvious to the POSA in light of the ’406 Publication.

326. In addition, as I explained above in Section VI.A.2.a.1)a), the ’406 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 4’s more particular form of inner wall canister support formation—namely, “a support rail

which extends longitudinally along an inside surface of the main body.” For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the ’406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing an inner wall canister support formation, let alone an inner wall canister support formation that “support rail which extends longitudinally along an inside surface of the main body.”

e) Claim 5

327. Asserted Claim 5 of the ’289 Patent depends from Asserted Claim 4 of the ’289 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” would not have been obvious to the POSA as a result of the ’406 Publication. *See supra* Section VI.A.2.a.1)d). Thus, Asserted Claim 5 would not have been obvious to the POSA in light of the ’406 Publication. For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the ’406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing an inner wall canister support formation, let alone an inner wall canister support formation that “includes a step formed thereon.”

f) Claim 6

328. Asserted Claim 6 of the ’289 Patent depends from Asserted Claim 4 of the ’289 Patent and recites: “The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” would not have been obvious to the POSA as a result of the ’406 Publication. *See supra* Section VI.A.2.a.1)d). Thus, Asserted Claim 6 would not have been obvious to the POSA in light of the ’406 Publication.

329. In addition, as I explained above, the '406 Publication does not disclose an inner wall canister support formation, and therefore does not disclose claim 6's requirement for a "plurality of support rails each of which extends longitudinally along an inside surface of the main body." For all the reasons I described above with respect to claim 1, the POSA would not have had a reason to alter the disclosure of the '406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Indeed, the POSA would have resisted this more dramatic change to the canister housing of the '406 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above. *Supra* Sections VI.A.2 and Section V.

g) Claim 7

330. Asserted Claim 7 of the '289 Patent depends from Asserted Claim 6 of the '289 Patent and recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." In my opinion, at a minimum, the "inhaler as claimed in claim 6" would not have been obvious to the POSA in in light of the '406 Publication. *See supra* Section VI.A.2.a.1)f). Thus, Asserted Claim 7 would not have been obvious to the POSA in light of the '406 Publication.

331. In addition, as I explained above, the '406 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 7's requirement for a "plurality of support rails" "wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the '406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Thus, the POSA would have resisted this more dramatic change to the canister housing of the '406

Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above. *Supra* Sections VI.A.2 and Section V.

h) Claim 8

332. Asserted Claim 8 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA as a result of the '406 Publication. *See supra* Section VI.A.2.a.1)d). Thus, Asserted Claim 8 would not have been obvious to the POSA in light of the '406 Publication.

333. In addition, as I explained above, the '406 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 8's more particular requirement for an inner wall canister support formation of a given shape—namely, a rail with two steps. For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the '406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing an inner wall canister support formation. Mr. Anderson is also incorrect that "Plaintiffs have interpreted step to include both the top of a support rail, and the bottom. As support rails will necessarily have a beginning and end, it would have been obvious for a POSA to include support rails including two steps formed thereon in the actuator of the '406 Publication." Anderson Opening Rep. ¶ 179. Not all beginning and ends of support rails are "steps" within the meaning of Teva's construction. For example, the base of the support rails of the '514 Publication are not "a location of changing width dimension thereon" because they run into the base of the inhaler at a constant width. Certainly, not all support rails contain two steps and Mr. Anderson has identified no reason why the POSA would have chosen to remove the dose counter of the '406 Publication from its disclosed housing

(containing no support rails) and place it into a housing containing a support rail with two steps.

2) The '587 Patent

334. Mr. Anderson argues that the '406 Publication renders obvious Asserted Claims 1-8 and 11-22 of the '587 patent. I disagree, and I incorporate by reference my analysis of the '406 Publication in Section IV.A as though fully set forth herein. I have not reproduced it here solely for the sake of brevity. I also incorporate as though set forth herein my analyses of the other references to which Mr. Anderson refers in his discussion of this obviousness theory—including my analyses of the '998 Patent in Section IV.E, the '008 Publication in Section IV.G, the '822 Patent in Section IV.H, the '668 Patent in Section IV.K, the '260 Publication in Section IV.L, Lewis in Section IV.W, and the '514 Publication in Section IV.C. Again, I do not reproduce those sections here solely for the sake of brevity.

a) Claim 1

335. As I explain above, Asserted Claim 1 of the '587 Patent is materially identical to claim 1 of the '289 Patent, except that Asserted Claim 1 of the '587 Patent adds the additional limitation that “the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

336. Because Asserted Claim 1 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that Asserted Claim 1 of the '587 Patent would not have been obvious in light of the '406 Publication. I incorporate by reference my analysis with respect to Claim 1 of the '289 patent in Section VI.A.2.a.1)a) as though fully set forth herein, and I do not repeat it solely for the sake of brevity.

337. Furthermore, the '406 Publication fails to disclose or otherwise suggest the arrangement of an inner wall canister support formation such that it “protects against unwanted

actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

338. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the ’406 Publication because the ’406 Publication “discloses, or renders obvious, every structural element” of the claim and these structural elements necessarily “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” *See* Anderson Opening Rep. ¶ 183.

339. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler) that the ’289 Patent does not require. I incorporate my analysis in Section VI.A.1.a.1)a) by reference as though fully set forth herein, and do not repeat it here solely for the sake of brevity.

340. Regardless, I disagree that the ’406 Publication “discloses, or renders obvious, every structural element” of the claim—as I described above, the ’406 Publication fails to disclose several limitations of Asserted Claim 1.

341. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products

meet this limitation.

342. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



343. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

344. Accordingly, even if the POSA had reason to modify the disclosure of the '406 Publication by transferring the dose counter it discloses into a canister housing that includes an inner wall canister support formation (and for the reasons described above, the POSA would not

have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler” as Asserted Claim 1 of the ’587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the ’587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the ’406 Publication in the manner Mr. Anderson suggests.

b) Claim 2

345. Asserted Claim 2 of the ’587 Patent depends from Asserted Claim 1 of the ’587 Patent and recites: “The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.a.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 2 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 2 of the ’587 Patent. *See supra* Section VI.A.2.a.1)b).

c) Claim 3

346. Asserted Claim 3 of the ’587 Patent depends from Asserted Claim 1 of the ’587

Patent and recites: “The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.a.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 3 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 3 of the ’587 Patent. *See supra* Section VI.A.2.a.1)c).

d) Claim 4

347. Asserted Claim 4 of the ’587 Patent depends from Asserted Claim 1 of the ’587 Patent and recites: “The inhaler as claimed in claim 1, first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section Section VI.A.2.a.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 4 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 4 of the ’587 Patent. *See supra* Section VI.A.2.a.1)d).

e) Claim 5

348. Asserted Claim 5 of the ’587 Patent depends from Asserted Claim 4 of the ’587

Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.a.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 5 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 5 of the ’587 Patent. *See supra* Section VI.A.2.a.1)e).

f) Claim 6

349. Asserted Claim 6 of the ’587 Patent depends from Asserted Claim 4 of the ’587 Patent and recites: “The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.a.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 6 of the ’587 Patent. *See supra* Section VI.A.2.a.1)f).

g) Claim 7

350. Asserted Claim 7 of the ’587 Patent depends from Asserted Claim 6 of the ’587 Patent and recites: “The inhaler as claimed in claim 6, wherein two of the plurality of support rails

are positioned at opposite ends of the inside surface of the main the body to face each other.” In my opinion, at a minimum, the “inhaler as claimed in claim 6” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)f). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.a.2)f) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 7 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 6 of the ’587 Patent. *See supra* Section VI.A.2.a.1)g).

h) Claim 8

351. Asserted Claim 8 of the ’587 Patent depends from Asserted Claim 4 of the ’587 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the ’406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.a.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 6 of the ’587 Patent. *See supra* Section VI.A.2.a.1)h).

i) Claim 11

352. Asserted Claim 11 of the ’587 Patent depends from Asserted Claim 1 of the ’587 Patent and recites: “The inhaler as claimed in claim 1 further comprising a second inner wall

canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.”

353. In my opinion, at a minimum, the dose counter claimed in Asserted Claim 1 of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)a). Thus, Asserted Claim 11 of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication.

354. In addition, as I explained above, the ’406 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 11’s requirement for a “second inner wall canister support formation,” let alone a configuration “wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.” For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the ’406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Indeed, the POSA would have resisted this more dramatic change to the canister housing of the ’406 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above. *Supra* Sections VI.A.2 and Section V.

j) Claim 12

355. Asserted Claim 12 of the ’587 Patent is materially identical to Asserted Claim 1 of the ’289 Patent, except that Asserted Claim 12 of the ’587 Patent adds the additional limitation “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

356. Because Asserted Claim 12 of the ’587 Patent contains every limitation of Asserted

Claim 1 of the '289 Patent, I conclude for the reasons I described above in Section in Section VI.A.2.a.1)a) that Asserted Claim 12 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. I incorporate by reference as though fully set forth herein my analysis in Section VI.A.2.a.1)a), and I do not reproduce it here solely for the sake of brevity.

357. In addition, the '406 Publication fails to render obvious Asserted Claim 12 of the '587 Patent because the '406 Publication does not disclose or otherwise suggest an inhaler configuration “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

358. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '406 Publication because the '406 Publication “discloses every structural element” of the claim and these structure elements necessarily protect against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. Anderson Opening Rep. ¶ 183.

359. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member) that the '289 Patent does not require.

360. Regardless, I disagree that the '406 Publication “discloses every structural element” of the claim—as I described above, the '406 Publication fails to disclose several limitations of Asserted Claim 1 of the '289 Patent and Asserted Claim 1 of the '587 Patent. I incorporate my analysis in Sections VI.A.1.a.1)a) and VI.A.1.a.2)a) by reference as though fully set forth herein, and do not repeat them here solely for the sake of brevity.

361. I also disagree that the mere presence of an inner wall canister support formation

that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation.

362. Mr. Anderson does not separately address Asserted Claim 12 in his analysis, instead conflating its final limitation with the final limitation of Asserted Claim 1. That is incorrect. Reducing rocking of the canister with respect to the main body of the inhaler is not the same as reducing rocking of the canister towards or away from the actuation member. To the contrary, the POSA would have understood that certain support rail configurations could achieve the former but not the latter. Nothing in the ’406 Publication discloses an inner wall canister support formation that prevents rocking of the canister towards or away from the actuation member.

363. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



364. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

365. Accordingly, even if the POSA had reason to modify the disclosure of the '406 Publication by transferring the dose counter it discloses into a canister housing that includes an inner wall canister support formation (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the '587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy.

Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the '406 Publication in the manner Mr. Anderson suggests.

k) Claim 13

366. Asserted Claim 13 recites:

13. An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a medicament canister retained in the canister housing and movable
relative thereto, and a dose counter, the dose counter having
an actuation member having at least a portion thereof located
in the canister housing for operation by movement of the
medicament canister,
wherein the canister housing has an inner wall, and a first inner wall
canister support formation extending inwardly from a main
surface of the inner wall,
wherein the canister housing has an aperture formed in the inner wall
through which the portion of the actuation member extends,
and
wherein the first inner wall canister support formation extends from
the main surface of the inner wall to the aperture.

367. As I described above with respect to Asserted Claim 1, the '406 Publication fails to disclose an "inner wall canister support formation" and the POSA would not have had reason to modify any device disclosed in the '406 Publication by transferring the dose counter in that device to a canister housing containing inner wall canister support formations. I incorporate that analysis herein, and therefore conclude that Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

l) Claim 14

368. Asserted Claim 14 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)k). Thus, Asserted Claim 14 of the '587 Patent would not have been

obvious to the POSA in light of the '406 Publication.

369. In addition, the '406 Publication fails to render obvious Asserted Claim 14's dependent limitation, for the reasons I addressed in Section VI.A.2.a.1)b), with respect to the same limitation in the context of Asserted Claim 2 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

m) Claim 15

370. Asserted Claim 15 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)k). Thus, Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

371. In addition, the '406 Publication fails to render obvious Asserted Claim 15's dependent limitation, for the reasons I addressed in Section VI.A.2.a.1)d), with respect to the same limitation in the context of Asserted Claim 4 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

n) Claim 16

372. Asserted Claim 16 of the '587 Patent depends from Claim 15 and recites: "The inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)m). Thus, Asserted Claim 16 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

373. In addition, the '406 Publication fails to render obvious Asserted Claim 16's dependent limitation, for the reasons I addressed in Section VI.A.2.a.1)e), with respect to the same limitation in the context of Asserted Claim 5 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

o) Claim 17

374. Asserted Claim 17 of the '587 Patent depends from Asserted Claim 15 and recites: "The inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)m). Thus, Asserted Claim 17 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

375. In addition, the '406 Publication fails to render obvious Asserted Claim 17's dependent limitation, for the reasons I addressed in Section VI.A.2.a.1)f) with respect to the same limitation in the context of Asserted Claim 6 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

p) Claim 18

376. Asserted Claim 18 of the '587 Patent depends from Claim 17 and recites: "The inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 17 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)o). Thus, Asserted Claim 18 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

377. In addition, the '406 Publication fails to render obvious Asserted Claim 18's

dependent limitation, for the reasons I addressed in Section VI.A.2.a.1)g), with respect to the same limitation in the context of Asserted Claim 7 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

q) Claim 19

378. Asserted Claim 19 of the '587 Patent depends from Asserted Claim 15 and recites: “The inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)m). Thus, Asserted Claim 19 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

379. In addition, the '406 Publication fails to render obvious Asserted Claim 19's dependent limitation, for the reasons I addressed in Section VI.A.2.a.1)h), with respect to the same limitation in the context of Asserted Claim 8 of the '289 Patent. I incorporate that analysis by reference here.

r) Claim 20

380. Asserted Claim 20 of the '587 Patent depends from Asserted Claim 15 and recites: “The inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)m). Thus, Asserted Claim 20 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

381. In addition, the '406 Publication fails to render obvious the limitation “wherein a

width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” As I describe above with respect to Asserted Claim 1 of the ’289 Patent, the ’406 Publication fails to disclose or render obvious the inclusion of *any* inner wall canister support formation, let alone one with the particular characteristics claimed in Asserted Claim 20. Mr. Anderson offers no reason why the POSA would have selected a support rail with this particular configuration.

s) Claim 21

382. Asserted Claim 21 of the ’587 Patent depends from Asserted Claim 13 and recites: “The inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication. *See supra* Section VI.A.2.a.2)k). Thus, Asserted Claim 21 of the ’587 Patent would not have been obvious to the POSA in light of the ’406 Publication.

383. In addition, the ’406 Publication fails to render obvious the “wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.” Since the aperture of Asserted Claim 21 is the aperture through which the actuation member of the dose counter extends, the aperture of Asserted Claim 21 is located in the same place as the actuation member. As I described above with respect to Asserted Claim 1 of the ’289 Patent, the ’406 Publication does not render obvious an inhaler in which the actuation member, center of the central outlet port, and an inner wall canister support formation lie in a common plane. I

incorporate that analysis here by reference.

t) Claim 22

384. Asserted Claim 22 of the '587 Patent depends from Asserted Claim 21 of the '587 Patent and recites: "The inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 21 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication. *See supra* Section VI.A.2.a.2)s). Thus, Asserted Claim 22 of the '587 Patent would not have been obvious to the POSA in light of the '406 Publication.

385. In addition, the '406 Publication fails to render obvious the limitation of Asserted Claim 22 requiring "a second inner wall canister support formation" and the limitation requiring that "the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X." I addressed these limitations in the context of Asserted Claim 11 of the '587 Patent above, and I incorporate that analysis by reference here.

b. The '514 Publication in Combination with the '406 Publication Does Not Render Obvious the Asserted Claims of the '289 and '587 Patents

1) The '289 Patent

386. Mr. Anderson asserts that the '514 Publication in combination with the '406 Publication renders obvious Asserted Claims of the '289 Patent. I disagree, and I incorporate by reference my analysis of the '406 Publication in Section IV.A and my analysis of the '514 Publication in Section IV.C as though fully set forth herein. I have not reproduced those sections here solely for the sake of brevity.

a) Claim 1

387. Mr. Anderson again incorrectly asserts that the '514 Publication discloses every limitation of Asserted Claim 1 of the '289 Patent. I explained at length that the '514 Publication failed to disclose every limitation of Asserted Claim 1 above, *supra* Section VI.A.1.b.1)a), and I incorporate that discussion here as if set forth fully herein. I have not repeated them solely for the sake of brevity.

388. In addition, Mr. Anderson suggests that the skilled person would have had a reason to combine the dose counter of the '406 Publication with the actuator of the '514 Publication, and that this combination would have resulted in the invention of Asserted Claim 1. I disagree for several reasons, including because the POSA would not have had reason to select the dose counter of the '406 Publication for modification. *Supra* Sections V and VI.A.2. I incorporate by reference my analyses in Section V and VI.A.2 as though fully set forth herein, and I do not reproduce it here solely for the sake of brevity.

389. The POSA would not have viewed the dose counter of the '406 Publication as compatible with the design of the actuator of the '514 Publication. The '514 Publication emphasizes the importance of affixing its dose indicator to the medication canister, such that neither is movable relative to the other—fundamentally, the '514 Publication is directed to an annular dose indicator, not canister housing design. The dose counters disclosed in the '406 Publication are not affixed to the canister, but rather the canister moves toward and away from the dose counter of the '406 Publication as the POSA actuates the device. Accordingly, the POSA would not have reason to combine one of the dose counters disclosed in the '406 Publication with the inhaler bodies disclosed in the '514 Publication, nor would the POSA reasonably have expected success in doing so. To the contrary, the POSA would have expected that combining a housing designed to accommodate an annular dose counter affixed to the canister with a different dose

counter located substantially below the canister would have been unsuccessful, if not inoperable. As the POSA would have understood, inhaler components must be tailored to work with a given dose counter, and dose counter components must be tailored to work with a given canister housing, valve, etc. As the '514 Publication explains, the POSA would have expected that the body of the inhalers disclosed in the '514 Publication would not have accommodated the dose counter of the '406 Publication, since locating the dose counter below the canister often requires "modification of adaptor geometry." '514 Publication, 3:5-10.

390. In addition, POSA would have understood that the close fit between the annular dose counter affixed to the canister and the canister housing acted to stabilize the canister within the canister housing. Accordingly, the POSA would have expected the canister housing of the '514 publication to be unsuitable for any design that did not stabilize the canister in this manner. The POSA therefore would not have had a reasonable expectation of success in achieving a robust and accurate inhaler/dose counting system by combining the canister housing disclosed in the '514 Publication with a dose counter, like the ones disclosed in the '406 Publication, that was not affixed to the canister and could not be expected to stabilize it within the canister housing accordingly.

391. Furthermore, the POSA would not have reasonably expected success in combining inhaler bodies of the '514 Publication with the dose counter of the '406 Publication because the inhaler bodies of the '514 Publication contain an "actuation pin" that is configured to be "received within the dose indicator, e.g. passing through a cut-out portion (66) in the second edge (62) of the housing (see Figure 5)." '514 Publication, 25:24-27. The POSA would have understood that such a pin would have been structurally incompatible with the dose counters disclosed in the '406 Publication. The POSA would have expected "actuation pin (29)" to physically prevent insertion of the dose counters disclosed in the '406 Publication appropriately

into the canister housing.

392. Furthermore, the '514 Publication discloses numerous housings, many of which do not have support rails, *see, e.g.*, '514 Publication, Figures 2b, 3, 8b, 10, and 12a, and it mentions support rails only once in its entire disclosure as an optional feature of the housing, unrelated to the dose indicator the '514 Publication devotes the remainder of its disclosure to describing. Thus, the POSA would not have had reason to (1) select one of the embodiments in the '514 Publication that discloses support rails, and then (2) modify that embodiment by eliminating the feature that is the primary subject of the '514 Publication's disclosure (its annular dose indicator), and then (3) integrate a dramatically different dose counter (such as that of the '406 Publication, which is affixed to the canister housing and is not affixed to the medication canister) into the canister housing of the '514 Publication. To the contrary, the POSA would not have expected such a combination to be operable, let alone successful.

393. Even were the POSA to have combined the dose counter of the '406 Publication with the canister housing of the '514 Publication, that combination would not have resulted in the claimed invention. There would have been many ways to align the actuation members of the dose counters of the '406 Publication with the optional inner wall canister support formations of the '514 Publication's canister housing, and the POSA would have had no reason to select an alignment that satisfies the Common Plane Limitation. To the contrary, neither the '406 Publication nor the '514 Publication suggested the importance of aligning support rails with any aspect of a dose counter or indicator, nor did they disclose the need to minimize canister rocking in connection with the addition of a dose counter, let alone suggest the use of canister support rails to do so. Indeed, the POSA would not have expected the devices disclosed in the '514 Publication to experience problems of the canister rocking in connection with the dose indicator, because the

canister and does indicator were affixed together. Nor would the POSA have expected the devices disclosed in the '406 Publication to experience such problems, since the actuation member(s) of the dose counter of the '406 Publication would have been expected to contact the medication canister symmetrically.

b) Claim 2

394. Asserted Claim 2 depends from Asserted Claim 1 and recites: “[t]he inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)a).

c) Claim 3

395. Asserted Claim 3 of the '289 Patent depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)a). Thus, Asserted Claim 3 would not have been obvious to the POSA in light of the '406 Publication.

d) Claim 4

396. Asserted Claim 4 of the '289 Patent depends from Asserted Claim 1 of the '289 Patent and recites: “The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)a). Thus, Asserted Claim 4 would not have been

obvious to the POSA in light of the '406 Publication.

e) Claim 5

397. Asserted Claim 5 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)d). Thus, Asserted Claim 5 would not have been obvious to the POSA in light of the '406 Publication.

f) Claim 6

398. Asserted Claim 6 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)d). Thus, Asserted Claim 6 would not have been obvious to the POSA in light of the '406 Publication.

g) Claim 7

399. Asserted Claim 7 of the '289 Patent depends from Asserted Claim 6 of the '289 Patent and recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." In my opinion, at a minimum, the "inhaler as claimed in claim 6" would not have been obvious to the POSA in in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)f). Thus, Asserted Claim 7 would not have been obvious to the POSA in light of the '406 Publication.

h) Claim 8

400. Asserted Claim 8 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.1)d). Thus, Asserted Claim 8 would not have been obvious to the POSA in light of the '406 Publication.

2) The '587 Patent

401. Mr. Anderson asserts that the '514 Publication in combination with the '406 Publication renders obvious Asserted Claims of the '587 Patent. I disagree, and I incorporate by reference my analysis of the '406 Publication in Section IV.A and my analysis of the '514 Publication in Section IV.C as though fully set forth herein. I have not reproduced those sections here solely for the sake of brevity.

a) Claim 1

402. As I explain above, Asserted Claim 1 of the '587 Patent is materially identical to Asserted Claim 1 of the '289 Patent, except that Asserted Claim 1 of the '587 Patent adds the additional limitation that "the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler."

403. Because Asserted Claim 1 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that Asserted Claim 1 of the '587 Patent would not have been obvious in light of the '406 Publication. I incorporate by reference my analysis in Section VI.A.2.b.1)a) as though fully set forth herein, and do not repeat

it here solely for the sake of brevity.

404. Furthermore, the '406 Publication fails to disclose or otherwise suggest the arrangement of an inner wall canister support formation such that it protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” I explained this in detail in Sections VI.A.1.a.1)a) and I incorporate that analysis by reference as though fully set forth herein. I do not repeat it here solely for the sake of brevity.

405. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '406 Publication because the '406 Publication “discloses, or renders obvious, every structural element” of the claim and these structural elements necessarily “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” Anderson Opening Rep. ¶ 221.

406. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler) that the '289 Patent does not require.

407. Regardless, I disagree that the '406 Publication “discloses, or renders obvious, every structural element” of the claim—as I described above, the '406 Publication fails to disclose several limitations of Asserted Claim 1. I explained this in detail in Section VI.A.1.a.1)a) and I incorporate that analysis by reference as though fully set forth herein. I do not repeat it here solely for the sake of brevity.

408. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of

the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation.

409. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



410. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor

inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

411. Accordingly, even if the POSA had reason to modify the disclosure of the '406 Publication by transferring the dose counter it discloses into a canister housing that includes an inner wall canister support formation (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the '587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the '406 Publication in the manner Mr. Anderson suggests.

b) Claim 2

412. Asserted Claim 2 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: “The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.b.2)a) above into

this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 2 of the '289 Patent, which contains the same additional limitation as Asserted Claim 2 of the '587 Patent.

c) Claim 3

413. Asserted Claim 3 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." In my opinion, at a minimum, the "inhaler as claimed in claim 1" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.b.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 3 of the '289 Patent, which contains the same additional limitation as Asserted Claim 3 of the '587 Patent.

d) Claim 4

414. Asserted Claim 4 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1, first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 1" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I

incorporate all of my analysis as set forth in Section VI.A.2.b.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 4 of the '289 Patent, which contains the same additional limitation as Asserted Claim 4 of the '587 Patent.

e) Claim 5

415. Asserted Claim 5 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.b.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 5 of the '289 Patent, which contains the same additional limitation as Asserted Claim 5 of the '587 Patent.

f) Claim 6

416. Asserted Claim 6 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: “The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I incorporate all

of my analysis as set forth in Section VI.A.2.b.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the '289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

g) Claim 7

417. Asserted Claim 7 of the '587 Patent depends from Asserted Claim 6 of the '587 Patent and recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." In my opinion, at a minimum, the "inhaler as claimed in claim 6" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)f). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.b.2)f) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 7 of the '289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

h) Claim 8

418. Asserted Claim 8 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. I

incorporate all of my analysis as set forth in Section VI.A.2.b.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the '289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

i) Claim 11

419. Asserted Claim 11 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: “The inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.”

420. In my opinion, at a minimum, the dose counter claimed in Asserted Claim 1 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)a). Thus, Asserted Claim 11 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

421. In addition, as I explained above, the '406 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 11's requirement for a “second inner wall canister support formation,” let alone a configuration “wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.” For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the '406 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Indeed, the POSA would have resisted this more dramatic change to the

canister housing of the '406 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above.

j) Claim 12

422. Asserted Claim 12 of the '587 Patent is materially identical to Asserted Claim 1 of the '289 Patent, except that Asserted Claim 12 of the '587 Patent adds the additional limitation “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

423. Because Asserted Claim 12 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above in Section)2)a)that Asserted Claim 12 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

424. In addition, the '514 Publication in combination with the '406 Publication fails to render obvious Asserted Claim 12 of the '587 Patent because neither Publication discloses or otherwise suggest an inhaler configuration “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

425. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '406 Publication because the '406 Publication “discloses every structural element” of the claim and these structural elements necessarily protect against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. Anderson Opening Rep. ¶ 221.

426. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member) that the '289 Patent does not require.

427. Regardless, I disagree that the combination of the '514 Publication and the '406 Publication “discloses every structural element” of the claim—as I described above, these references not disclose the Common Plane Limitation either alone or in combination.

428. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation.

429. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



430. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been

depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

431. Mr. Anderson does not separately address Asserted Claim 12 in his analysis, instead conflating its final limitation with the final limitation of Asserted Claim 1. That is incorrect. Reducing rocking of the canister with respect to the main body of the inhaler is not the same as reducing rocking of the canister towards or away from the actuation member. To the contrary, the POSA would have understood that certain support rail configurations could achieve the former but not the latter. Nothing in the '514 Publication or the '406 Publication (alone or in combination) discloses an inner wall canister support formation that prevents rocking of the canister towards or away from the actuation member.

432. Accordingly, even if the POSA had reason to modify the disclosure of the '406 Publication by transferring the dose counter it discloses into an inhaler of the '514 Publication (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the

'587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the '406 Publication in the manner Mr. Anderson suggests.

k) Claim 13

433. Asserted Claim 13 recites:

13. An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a medicament canister retained in the canister housing and movable
relative thereto,
and a dose counter, the dose counter having an actuation member
having at least a portion thereof located in the canister
housing for operation by movement of the medicament
canister,
wherein the canister housing has an inner wall, and a first inner wall
canister support formation extending inwardly from a main
surface of the inner wall, wherein the canister housing has
an aperture formed in the inner wall through which the
portion of the actuation member extends, and wherein the
first inner wall canister support formation extends from the
main surface of the inner wall to the aperture.

434. As I described above with respect to Asserted Claim 1, the '406 Publication fails to disclose an “inner wall canister support formation” and the POSA would not have had reason to modify any device disclosed in the '406 Publication by transferring the dose counter in that device to a canister housing of the '514 publication. I incorporate that analysis herein, and therefore conclude that Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

l) Claim 14

435. Asserted Claim 14 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)k). Thus, Asserted Claim 14 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

436. In addition, the combination of the '514 Publication and the '406 Publication fails to render obvious Asserted Claim 14's dependent limitation, for the reasons I addressed in Section VI.A.2.b.1)b), with respect to the same limitation in the context of Asserted Claim 2 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

m) Claim 15

437. Asserted Claim 15 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)k). Thus, Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

438. In addition, the combination of the '514 Publication and the '406 Publication fails to render obvious Asserted Claim 15's dependent limitation, for the reasons I addressed in Section VI.A.2.b.1)d), with respect to the same limitation in the context of Asserted Claim 4 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

n) Claim 16

439. Asserted Claim 16 of the '587 Patent depends from Claim 15 and recites: "The inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)m). Thus, Asserted Claim 16 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

440. In addition, the combination of the '514 Publication with the '406 Publication fails to render obvious Asserted Claim 16's dependent limitation, for the reasons I addressed in Section VI.A.2.b.1)e), with respect to the same limitation in the context of Asserted Claim 5 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

o) Claim 17

441. Asserted Claim 17 of the '587 Patent depends from Asserted Claim 15 and recites: "The inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.a.2)m). Thus, Asserted Claim 17 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

442. In addition, the '514 Publication in combination with the '406 Publication fails to render obvious Asserted Claim 17's dependent limitation, for the reasons I addressed in Section VI.A.2.b.1)f) with respect to the same limitation in the context of Asserted Claim 6 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

p) Claim 18

443. Asserted Claim 18 of the '587 Patent depends from Claim 17 and recites: "The inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 17 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* VI.A.2.b.2)o). Thus, Asserted Claim 18 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

444. In addition, the '514 Publication in combination with the '406 Publication fails to render obvious Asserted Claim 18's dependent limitation, for the reasons I addressed in Section VI.A.2.b.1)g), with respect to the same limitation in the context of Asserted Claim 7 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

q) Claim 19

445. Asserted Claim 19 of the '587 Patent depends from Asserted Claim 15 and recites: "The inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)m). Thus, Asserted Claim 19 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

446. In addition, the '514 Publication in combination with the '406 Publication fails to render obvious Asserted Claim 19's dependent limitation, for the reasons I addressed in Section VI.A.2.b.1)h), with respect to the same limitation in the context of Asserted Claim 8 of the '289

Patent. I incorporate that analysis by reference here.

r) Claim 20

447. Asserted Claim 20 of the '587 Patent depends from Asserted Claim 15 and recites: “The inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)m). Thus, Asserted Claim 19 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

448. In addition, the '406 Publication fails to render obvious the limitation “wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” The '406 Publication fails to disclose or render obvious the inclusion of *any* inner wall canister support formation, let alone one with the particular characteristics claimed in Asserted Claim 20. The '514 Publication simply never reports the dimensions of its support rails, nor is it apparent where in the inhaler bodies of the '514 Publication the dose counters of the '406 publication would rest, and therefore it is not apparent whether the width dimension of the support rail would be greatest “at the location where the support rail is closest to the aperture.”

s) Claim 21

449. Asserted Claim 21 of the '587 Patent depends from Asserted Claim 13 and recites: “The inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X

which passes through the center of the central outlet port.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’406 Publication. *See supra* Section VI.A.2.b.2)k). Thus, Asserted Claim 21 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’406 Publication.

450. In addition, the combination of the ’514 Publication and ’406 Publication fails to render obvious the “wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.” Since the aperture of Asserted Claim 21 is the aperture through which the actuation member of the dose counter extends, the aperture of Asserted Claim 21 is located in the same place as the actuation member. As I described above with respect to Asserted Claim 1 of the ’289 Patent, which analysis I incorporate by reference as though fully set forth herein, the ’514 Publication in combination with the ’406 Publication does not render obvious an inhaler in which the actuation member, center of the central outlet port, and an inner wall canister support formation lie in a common plane. I incorporate that analysis here by reference.

t) Claim 22

451. Asserted Claim 22 of the ’587 Patent depends from Asserted Claim 21 of the ’587 Patent and recites: “The inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 21 of the ’587 Patent would not have been obvious to the POSA in light of the

'514 Publication in combination with the '406 Publication. *See supra* Section VI.A.2.b.2)s). Thus, Asserted Claim 22 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '406 Publication.

452. In addition, the combination of the '514 Publication with the '406 Publication fails to render obvious the limitation of Asserted Claim 22 requiring “a second inner wall canister support formation” and the limitation requiring that “the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X.” I addressed these limitations in the context of Asserted Claim 11 of the '587 Patent above, and I incorporate that analysis by reference here.

c. The '021 Publication Does Not Render Obvious the Asserted Claims of the '289 and '587 Patents

1) The '289 Patent

453. Mr. Anderson asserts that Asserted Claims 1-8 of the '289 Patent would have been obvious in light of the '021 Publication. I disagree, and I incorporate by reference my analysis of the '021 Publication in Section IV.D as though fully set forth herein, and I have not reproduced it here solely for the sake of brevity. I also incorporate as though set forth herein my analyses of the other references to which Mr. Anderson refers in his discussion of this obviousness theory—including my analyses of the '998 Patent in Section IV.E, the '008 Publication in Section IV.G, the '822 Patent in Section IV.H, the '668 Patent in Section IV.K, the '260 Publication in Section IV.L, Lewis in Section IV.W, and the '514 Publication in Section IV.C. Again, I do not reproduce those sections here solely for the sake of brevity.

a) Claim 1

454. The '021 Publication does not disclose an inner wall canister support formation.

Mr. Anderson appears to agree—he does not identify any disclosure in the '021 Publication that he asserts is a disclosure of an inner wall canister support formation. Instead, Mr. Anderson suggests that the POSA would have had reason to remove the dose counter of the '021 Publication from the canister housing in which it was disclosed and add it to a canister housing containing an inner wall canister support formation. I disagree that the POSA would have had reason to select any particular dose counter of the '021 Publication for modification, and I disagree that the POSA would have had reason to add that dose counter to an inhaler with inner wall canister support formations, all with a reasonable expectation of success. The multiple decisions required to pursue such a combination were not supported by the prior art or understanding of the POSA; only hindsight knowledge of the invention would have justified that approach. In any event, the combination of the dose counter of the '021 Publication with an inhaler containing an inner wall canister support formation would not have led the POSA to the claimed inventions.

455. The POSA seeking to add a dose tracking device to an MDI would not have selected any one of the multiple dose counter embodiments disclosed in the '021 Publication for modification. *Supra* Section VI.A.2. The '021 Publication discloses dose indicators, *e.g.*, '021 Publication, ¶ [0096]—even had the POSA selected the embodiments of the '021 Publication for modification (and I do not agree that the POSA would have done so), the POSA would have selected dose indicator embodiments of the '021 Publication rather than dose counter embodiments. Even had the POSA chosen to pursue a dose counter, the POSA would have pursued a dose counter located on top of the canister, not a dose counter located in whole or in part below the canister—again, for all the reasons I explained. *Supra* Section VI.A.2. The '021 Publication does not meet this criterion, and the POSA would not have selected it for further modification.

456. As I describe above, *supra* Section V, I also disagree with Mr. Anderson's assertion

that “inner wall canister support formations” were “essentially ubiquitously used in MDIs” as of the priority date. To the contrary, many of the prior art references Mr. Anderson selected to support his opinions in this case describe inhalers without any reference to “inner wall canister support formations” or do not include such formations in embodiments with dose counters. *See, e.g.*, ’406 Publication (depicting and describing inhalers without rails extending outwardly from the main body); ’044 Publication (same); ’817 Publication (same); ’021 Publication (same); ’191 Publication (Figures 31, 32, 70, 71, 73-76, 93, 136, depicting a canister housing without support rails); ’552 Publication; ’950 Publication; ’627 Patent; GB ’489; ’159 Publication; ’965 Publication; and ’102 Publication (as I explained in detail above in Sections IV and V, which I incorporate by reference as though fully set forth herein). Other references described such ribs as optional. *See* ’008 Publication, ¶ [0045] (“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”). Publication, ’Other references described such ribs as optional. *See* ’008 Publication, ¶ [0045] (“Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1.”); *see also* ’514 Publication at 14:17-19; ’822 Patent, 3:11-14. As those examples from Mr. Anderson’s references alone reflect, inner wall canister support formations were anything but ubiquitous. Even today, inhalers are marketed without “inner wall canister support formations”—i.e., support rails. *See* Exhibit B.

457. Furthermore, the POSA would have resisted changing the canister housing associated with the dose counter of the ’021 Publication, or adding any structure to the canister housing of a different inhaler. As the POSA would have understood, components of a system are designed and disclosed to be used together, not to be mixed and matched from different systems or modified in ways that could alter critical features like the established airflow through the

inhaler, which can affect product performance and/or require further regulatory approvals. *See, e.g.,* Stuart 2013 at 43, TEVADOC-00000534. Simply put, the POSA who chose to use the dose counter of the '021 Publication would have used the canister housing described for use with the dose counter of the '021 Publication, rather than selecting some other canister housing or modifying the canister housing that the reference discloses. The POSA would have deemed Mr. Anderson's approach in this regard untenable and contrary to the disclosure and established, standard engineering principles applied as a matter of course in the field. In particular, the '021 Publication acknowledges that changes are required to the canister housing to incorporate the dose counters and indicators it discloses. In particular, the '021 Publication explains that such changes include "providing a viewing window in the housing in alignment with the module viewing window and the removal of any structure formed between the support block and outer wall of the housing." '021 Publication, [0136]. The POSA also would not have reasonably expected success in integrating the dose counter or indicator embodiments of the '021 Publication into a "conventional" canister housing because the POSA would have understood that the structures the '021 Publication discloses likely take up too much space to expect the combination to function properly. In particular, the POSA would have expected that either the embodiments of the '021 Publication would simply not fit in a conventional actuator, or the POSA would have expected that such a fit would be so snug that it would impede airflow. The '021 Publication also describes the shape of its dose counter housing as being adapted to the canister housing, and noted that the embodiments of the '021 Publication "can be configured in any number of different sizes and shapes so as to be accommodated in a variety of housings or cap assemblies, with or without support blocks and the like." '021 Publication, [0108]. This statement acknowledges that the dose counters and indicators disclosed by the '021 Publication

must be tailored to the particular canister housing in which they operate. That is consistent with my experience, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The POSA would not have reasonably expected success in adding a counter or indicator disclosed in the '021 Publication in a different canister housing without first adjusting both the canister housing and the dose indicator to work well with one another.

458. Mr. Anderson's opinion that it would have been a departure from known practice, and less likely to result in a successful product, for the POSA not to have modified the '021 Publication by removing its dose counter from the housing disclosed in the '021 Publication and placing the dose counter of the '021 Publication into a different canister housing that contained support rails. I disagree. As I explained above, successful products that do not include support rails are marketed today and many were marketed as of the priority date—for example, Atrovent®, Alupent®, Berodual®, Berotec®, Combivent®, and Budair® do not include support rails, and I have included images of each of these products in Exhibit B. And as

I stated before, the POSA would have been concerned that any alterations to the inside of the canister housing, such as the addition of support rails, would have raised issues regarding airflow disruption, alteration to product performance, or a need to seek new regulatory approvals. *See, e.g.,* Stuart 2013, at 43, TEVADOC-00000534. The POSA would have understood that the '021 Publication disclosed inhaler bodies that were suitable for use with its dose counters and dose indicators, not one that should be changed, at the risk of creating the foregoing problems.

459. Mr. Anderson states that “[t]he '021 Publication discloses spacing the canister from the housing walls. *See, e.g., id.* at [0108], claim 46. A POSA would have been motivated to use an actuator that includes ribs, or to modify the actuator of the '021 Publication to include ribs in order to maintain this space, support the canister, and minimize unwanted counting.” Anderson Opening Rep. ¶ 249. I disagree with Mr. Anderson that paragraph [0108] of the '021 Publication discloses “spacing the canister from the housing walls.” Rather, paragraph [0108] discloses space between the valve stem block and the canister walls such that the dose counter or indicator described by the '021 Publication can fit in the space between the valve stem block and the canister walls. It does not follow that the canister itself is spaced from the walls.

460. I also disagree that the “POSA would have been motivated to use an actuator that includes ribs, or to modify the actuator of the '021 Publication to include ribs in order to maintain this space, support the canister, and minimize unwanted counting.” Anderson Opening Rep. ¶ 249. Again, in my opinion, the '021 Publication does not disclose the presence of “space” “to be maintained.” '021 Publication, ¶ [0108]. Furthermore, the '021 Publication's total silence with respect to support rails and canister rocking also belies Mr. Anderson's suggestion that the POSA would have had reason to add the dose counter of the '021 Publication to a canister housing with support rails in order to prevent canister rocking—to the contrary, the POSA would have

understood canister rocking not to be a problem in connection with the canister housing and dose counter and indicator embodiments the '021 Publication discloses. As I have explained, several actuators marketed before the priority date and still marketed today use no rails to stabilize the canister and yet do not experience undue canister rocking. *See supra* Sections VI.A.2 and Section V. The POSA would not have had reason to depart from the inhaler bodies disclosed in the '021 Publication for use with the dose counters and indicators of the '021 Publication. I also disagree with Mr. Anderson's suggestion that the POSA would have had reason to place the dose counters or indicators of the '021 Publication into a canister housing with support rails in order to "minimize unwanted counting." '021 Publication, [0108]. Nothing in the '021 Publication mentions canister rocking at all, let alone connects the minimization of canister rocking with improving the accuracy of the dose counter. To the contrary, that is among those things disclosed for the first time by the named inventors of the Asserted Claims. Absent any suggestion in the prior art that counter accuracy would improve by altering the canister housing in which the dose counters or indicators of the '021 Publication is disclosed (and there is none), Mr. Anderson's statements rely only on hindsight. In my opinion, without the benefit of hindsight, and without any suggestion that the canister housing/dose counter combination disclosed in the '021 Publication suffered from deficiencies, the POSA would not have had reason to alter the canister housing that the '021 discloses is compatible with its dose counters and indicators. To the contrary, the POSA would have had many reasons to avoid making such modifications, including that the POSA would have been concerned such modifications would affect airflow through the device, would require new testing, and would require changes to the process by which the canister housing was manufactured, including a need for new molds to make the canister housing. The POSA would have sought to avoid such complications.

461. Even if the POSA chose to remove the dose counter or indicator disclosed by the '021 Publication and place that dose counter into a canister housing containing “ribs” (and for the reasons I explain above, the POSA would not have done so), Mr. Anderson identifies no reason at all why the POSA would have had selected a canister housing whose ribs would have happened to lie a common plane with actuation member of the '021 Publication's dose counter. No such reason exists in the prior art, and Mr. Anderson's argument thus relies only on hindsight. Indeed, Mr. Anderson's sole rationale for why the POSA would have aligned the inner wall canister support formations from one reference with the actuation member of a second reference is as follows: “A POSA would be aware that during transportation inhalers are jostled, causing the canister to move within the housing. It would have been obvious to a POSA to position a rib, or canister support formation, adjacent to the actuation member 74 in order to prevent the canister moving in a direction that would allow it to depress the actuation member, which could cause unwanted dose counting.” Anderson Opening Rep. ¶ 250.

462. First, a rib located “adjacent” to actuation member 74 would not necessarily satisfy the Common Plane Limitation—Mr. Anderson's theory falls short for this reason. Additionally, Mr. Anderson's theory simply adopts a benefit of the claimed invention as disclosed in the Asserted Patents but nowhere disclosed in the prior art as a reason to modify the prior art. Mr. Anderson has cited no prior art reference suggesting the POSA would have appreciated that the canister's rocking should be particularly controlled in the direction of the dose counter's actuation member, and I am aware of no evidence he could have cited. Indeed, Mr. Anderson has not identified a single prior art reference connecting rocking of the canister to dose counting accuracy. The named inventors of the Asserted Patent were the first to make that connection, and the claimed inventions are the result. For clarity, the '021 Publication does not even recognize inhaler

“jostling” as a design challenge that should be addressed.

463. The non-obviousness of Asserted Claim 1 is further confirmed by the inventors’ own experience. It was not until the inventors grappled with the results of integrating a dose counter into the canister housing, and had selected a dose counter with an actuation member extending into the canister housing operation by movement of the medicament canister, that the inventors recognized the benefit of adjusting the location of the support rails to accommodate the dose counter. In particular, after adding such a dose counter to an existing canister housing, the inventors appreciated the benefits of “locat[ing the rails] to minimize the wobble of the canister above the counter plunger” and of adding “additional rails . . . to prevent excessive wobble of the canister within the body.” TEVAQVAR-00031848, at -854. The prior art disclosed none of this experience, knowledge, data, and modification.

b) Claim 2

464. Asserted Claim 2 depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.1)a). Thus, Asserted Claim 2 would not have been obvious to the POSA in light of the ’021 Publication.

c) Claim 3

465. Asserted Claim 3 of the ’289 Patent depends from Asserted Claim 1 and recites: “The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” would not have been obvious to the POSA as a result of the ’021 Publication. *See supra* Section VI.A.2.c.1)a). Thus, Asserted Claim 3 would not have been obvious to the POSA in light of the ’021 Publication.

d) Claim 4

466. Asserted Claim 4 of the '289 Patent depends from Asserted Claim 1 of the '289 Patent and recites: "The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 1" would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.1)a). Thus, Asserted Claim 4 would not have been obvious to the POSA in light of the '021 Publication.

467. In addition, as I explained above, the '021 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 4's more particular form of inner wall canister support formation—namely, a support rail which extends longitudinally along an inside surface of the main body." For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the '021 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing an inner wall canister support formation, let alone an inner wall canister support formation that "support rail which extends longitudinally along an inside surface of the main body."

e) Claim 5

468. Asserted Claim 5 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA as a result of the '021 Publication. *See supra* Section VI.A.2.c.1)d). Thus, Asserted Claim 5 would not have been obvious to the POSA in light of the '021 Publication.

f) Claim 6

469. Asserted Claim 6 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA as a result of the '021 Publication. *See supra* Section VI.A.2.c.1)d). Thus, Asserted Claim 6 would not have been obvious to the POSA in light of the '021 Publication.

470. In addition, as I explained above, the '021 Publication does not disclose an inner wall canister support formation, and therefore does not disclose claim 6's requirement for a "plurality of support rails each of which extends longitudinally along an inside surface of the main body." For all the reasons I described above with respect to claim 1, the POSA would not have had a reason to alter the disclosure of the '021 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Indeed, the POSA would have resisted this more dramatic change to the canister housing of the '021 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above.

g) Claim 7

471. Asserted Claim 7 of the '289 Patent depends from Asserted Claim 6 of the '289 Patent and recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." In my opinion, at a minimum, the "inhaler as claimed in claim 6" would not have been obvious to the POSA in in light of the '021 Publication. *See supra* Section VI.A.2.c.1)f). Thus, Asserted Claim 7 would not have been obvious to the POSA in light of the '021 Publication.

472. In addition, as I explained above, the '021 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 7's requirement

for a “plurality of support rails” “wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other.” For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the ’021 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Thus, the POSA would have resisted this more dramatic change to the canister housing of the ’021 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above.

h) Claim 8

473. Asserted Claim 8 of the ’289 Patent depends from Asserted Claim 4 of the ’289 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” would not have been obvious to the POSA as a result of the ’021 Publication. *See supra* Section VI.A.2.c.1)d). Thus, Asserted Claim 8 would not have been obvious to the POSA in light of the ’021 Publication.

474. In addition, as I explained above, the ’021 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 8’s more particular requirement for an inner wall canister support formation of a given shape—namely, a rail with two steps. For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the ’021 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing an inner wall canister support formation. Mr. Anderson is also incorrect that “Plaintiffs have interpreted step to include both the top of a support rail, and the bottom. As support rails will necessarily have a beginning and end, it would have been obvious for a POSA to include support rails including two

steps formed thereon in the actuator of the '021 Publication.” Anderson Opening Rep. ¶ 179. Not all beginning and ends of support rails are ‘steps’ within the meaning of Teva’s construction. For example, the base of the support rails of the '514 Publication as depicted in Figure 8a are not “a location of changing width dimension thereon” because they run into the base of the inhaler at a constant width. Certainly, not all support rails contain two steps and Mr. Anderson has identified no reason why the POSA would have chosen to remove the dose counter of the '021 Publication from its disclosed housing (containing no support rails) and place it into a housing containing a support rail with two steps.

2) The '587 Patent

475. Mr. Anderson asserts that Asserted Claims of the '587 Patent would have been obvious in light of the '021 Publication. I disagree, and I incorporate by reference my analysis of the '021 Publication in Section IV.D as though fully set forth herein, and I have not reproduced it here solely for the sake of brevity. I also incorporate as though set forth herein my analyses of the other references to which Mr. Anderson refers in his discussion of this obviousness theory—including my analyses of the '998 Patent in Section IV.E, the '008 Publication in Section IV.G, the '822 Patent in Section IV.H, the '668 Patent in Section IV.K, the '260 Publication in Section IV.L, Lewis in Section IV.W, and the '514 Publication in Section IV.C. Again, I do not reproduce those sections here solely for the sake of brevity.

a) Claim 1

476. As I explain above, Asserted Claim 1 of the '587 Patent is materially identical to Claim 1 of the '289 Patent, except that Asserted Claim 1 of the '587 Patent adds the additional limitation that “the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

477. Because Asserted Claim 1 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that Asserted Claim 1 of the '587 Patent would not have been obvious in light of the '021 Publication.

478. Furthermore, the '021 Publication fails to disclose or otherwise suggest the arrangement of an inner wall canister support formation such that it “protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

479. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '021 Publication because the '021 Publication “discloses every structural element” of the claim and these structural elements necessarily “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” Anderson Opening Rep. ¶ 261.

480. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler) that the '587 Patent does not require.

481. Regardless, I disagree that the '021 Publication “discloses every structural element” of the claim—as I described above, the '021 Publication fails to disclose several limitations of Asserted Claim 1.

482. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” While the POSA would have been able, based on the teachings of the Asserted Patents,

to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants' products meet this limitation.

483. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



484. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

485. Accordingly, even if the POSA had reason to modify the disclosure of the '021 Publication by transferring the dose counter it discloses into a canister housing that includes an inner wall canister support formation (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the '587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the '021 Publication in the manner Mr. Anderson suggests.

b) Claim 2

486. Asserted Claim 2 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: “[t]he inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 2 of the '289 Patent, which contains the same additional limitation as Asserted

Claim 2 of the '587 Patent.

c) Claim 3

487. Asserted Claim 3 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: “The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 3 of the '289 Patent, which contains the same additional limitation as Asserted Claim 3 of the '587 Patent.

d) Claim 4

488. Asserted Claim 4 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: “The inhaler as claimed in claim 1, first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 1” of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 4 of the '289 Patent, which contains the same additional limitation as Asserted Claim 4 of the '587 Patent.

e) Claim 5

489. Asserted Claim 5 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the "inhaler as claimed in claim 4" of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 5 of the '289 Patent, which contains the same additional limitation as Asserted Claim 5 of the '587 Patent.

f) Claim 6

490. Asserted Claim 6 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the '289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

g) Claim 7

491. Asserted Claim 7 of the '587 Patent depends from Asserted Claim 6 of the '587 Patent and recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails

are positioned at opposite ends of the inside surface of the main the body to face each other. In my opinion, at a minimum, the “inhaler as claimed in claim 6” of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.2)f). Accordingly, this claim would not have been obvious to the POSA in light of the ’021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 7 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 6 of the ’587 Patent.

h) Claim 8

492. Asserted Claim 8 of the ’587 Patent depends from Asserted Claim 4 of the ’587 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the ’021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.c.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the ’289 Patent, which contains the same additional limitation as Asserted Claim 6 of the ’587 Patent.

i) Claim 11

493. Asserted Claim 11 of the ’587 Patent depends from Asserted Claim 1 of the ’587 Patent and recites: “The inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first

inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.”

494. In my opinion, at a minimum, the dose counter claimed in Asserted Claim 1 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.2)a). Thus, Asserted Claim 11 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication.

495. In addition, as I explained above, the ’021 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 11’s requirement for a “second inner wall canister support formation,” let alone a configuration “wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X.” For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the ’021 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Indeed, the POSA would have resisted this more dramatic change to the canister housing of the ’021 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above.

j) Claim 12

496. Asserted Claim 12 of the ’587 Patent is materially identical to Asserted Claim 1 of the ’289 Patent, except that Asserted Claim 12 of the ’587 Patent adds the additional limitation “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

497. Because Asserted Claim 12 of the ’587 Patent contains every limitation of Asserted Claim 1 of the ’289 Patent, I conclude for the reasons I described above that Asserted Claim 12 of

the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

498. In addition, the '021 Publication fails to render obvious Asserted Claim 12 of the '587 Patent because the '021 Publication does not disclose or otherwise suggest an inhaler configuration “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.”

499. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '021 Publication because the '021 Publication “discloses every structural element” of the claim and these structure elements necessarily protect against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. Anderson Opening Rep. ¶ 299.

500. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member) that the '289 Patent does not require.

501. Regardless, I disagree that the '021 Publication “discloses every structural element” of the claim—as I described above, the '021 Publication fails to disclose several limitations of Asserted Claim 1 of the '289 Patent and Asserted Claim 1 of the '587 Patent.

502. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and

canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants' products meet this limitation.

503. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



504. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

505. Mr. Anderson does not separately address Asserted Claim 12 in his analysis, instead

conflating its final limitation with the final limitation of Asserted Claim 1. That is incorrect. Reducing rocking of the canister with respect to the main body of the inhaler is not the same as reducing rocking of the canister towards or away from the actuation member. To the contrary, the POSA would have understood that certain support rail configurations could achieve the former but not the latter. Nothing in the '021 Publication discloses an inner wall canister support formation that prevents rocking of the canister towards or away from the actuation member.

506. Accordingly, even if the POSA had reason to modify the disclosure of the '021 Publication by transferring the dose counter it discloses into a canister housing that includes an inner wall canister support formation (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in any prior art reference that identifies the problem solved by Asserted Claim 1 of the '587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the '021 Publication in the manner Mr. Anderson suggests.

k) Claim 13

507. Asserted Claim 13 recites:

13. An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,

a medicament canister retained in the canister housing and movable relative thereto,
and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

508. As I described above with respect to Asserted Claim 1, the '021 Publication fails to disclose an "inner wall canister support formation" and the POSA would not have had reason to modify any device disclosed in the '021 Publication by transferring the dose counter in that device to a canister housing containing inner wall canister support formations. I incorporate that analysis herein, and therefore conclude that Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

I) Claim 14

509. Asserted Claim 14 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)k). Thus, Asserted Claim 14 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

510. In addition, the '021 Publication fails to render obvious Asserted Claim 14's dependent limitation, for the reasons I addressed in Section VI.A.2.c.1)b), with respect to the same limitation in the context of Asserted Claim 2 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

m) Claim 15

511. Asserted Claim 15 of the '587 Patent depends from Asserted Claim 13 and recites: “The inhaler as claimed in claim 13, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)k). Thus, Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

512. In addition, the '021 Publication fails to render obvious Asserted Claim 15's dependent limitation, for the reasons I addressed in Section VI.A.2.c.1)d), with respect to the same limitation in the context of Asserted Claim 4 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

n) Claim 16

513. Asserted Claim 16 of the '587 Patent depends from Claim 15 and recites: “The inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)m). Thus, Asserted Claim 16 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

514. In addition, the '021 Publication fails to render obvious Asserted Claim 16's dependent limitation, for the reasons I addressed in Section VI.A.2.c.1)e), with respect to the same limitation in the context of Asserted Claim 5 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

o) Claim 17

515. Asserted Claim 17 of the '587 Patent depends from Asserted Claim 15 and recites: “The inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)m). Thus, Asserted Claim 17 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

516. In addition, the '021 Publication fails to render obvious Asserted Claim 17's dependent limitation, for the reasons I addressed in Section VI.A.2.c.1)f) with respect to the same limitation in the context of Asserted Claim 6 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

p) Claim 18

517. Asserted Claim 18 of the '587 Patent depends from Claim 17 and recites: “The inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 17 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)o). Thus, Asserted Claim 18 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

518. In addition, the '021 Publication fails to render obvious Asserted Claim 18's dependent limitation, for the reasons I addressed in Section VI.A.2.c.1)g), with respect to the same limitation in the context of Asserted Claim 7 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

q) Claim 19

519. Asserted Claim 19 of the '587 Patent depends from Asserted Claim 15 and recites:

“The inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.2)m). Thus, Asserted Claim 19 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication.

520. In addition, the ’021 Publication fails to render obvious Asserted Claim 19’s dependent limitation, for the reasons I addressed in Section VI.A.2.c.1)h), with respect to the same limitation in the context of Asserted Claim 8 of the ’289 Patent. I incorporate that analysis by reference here.

r) Claim 20

521. Asserted Claim 20 of the ’587 Patent depends from Asserted Claim 15 and recites: “The inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.2)m). Thus, Asserted Claim 19 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication.

522. In addition, the ’021 Publication fails to render obvious the limitation “wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” As I describe above with respect to Asserted Claim 1 of the ’289 Patent, the ’021 Publication fails to disclose or render obvious the inclusion of *any* inner wall canister support formation, let alone one with the particular characteristics claimed in Asserted Claim 20. Mr. Anderson offers no reason why the POSA would

have selected a support rail with this particular configuration.

s) Claim 21

523. Asserted Claim 21 of the '587 Patent depends from Asserted Claim 13 and recites: “The inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication. *See supra* Section VI.A.2.c.2)k). Thus, Asserted Claim 21 of the '587 Patent would not have been obvious to the POSA in light of the '021 Publication.

524. In addition, the '021 Publication fails to render obvious the “wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.” Since the aperture of Asserted Claim 21 is the aperture through which the actuation member of the dose counter extends, the aperture of Asserted Claim 21 is located in the same place as the actuation member. As I described above with respect to Asserted Claim 1 of the '289 Patent, the '021 Publication does not render obvious an inhaler in which the actuation member, center of the central outlet port, and an inner wall canister support formation lie in a common plane. I incorporate that analysis here by reference.

t) Claim 22

525. Asserted Claim 22 of the '587 Patent depends from Asserted Claim 21 of the '587 Patent and recites: “The inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first

inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 21 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication. *See supra* Section VI.A.2.c.2)s). Thus, Asserted Claim 22 of the ’587 Patent would not have been obvious to the POSA in light of the ’021 Publication.

526. In addition, the ’021 Publication fails to render obvious the limitation of Asserted Claim 22 requiring “a second inner wall canister support formation” and the limitation requiring that “the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X.” I addressed these limitations in the context of Asserted Claim 11 of the ’587 Patent above, and I incorporate that analysis by reference here.

d. The ’514 Publication in Combination with the ’021 Publication Does Not Render Obvious the Asserted Claims of the ’289 and ’587 Patents

1) The ’289 Patent

527. Mr. Anderson argues that the ’514 Publication in combination with the ’021 Publication renders obvious Asserted Claims of the ’289 patent. I disagree, and I incorporate by reference my analysis of the ’514 Publication in Section IV.A and my analysis of the ’021 Publication in Section IV.D as though fully set forth herein. I have not reproduced those sections here solely for the sake of brevity.

a) Claim 1

528. I explained at length above that the ’021 Publication failed to disclose every limitation of Asserted Claim 1 above, *supra* Section VI.A.1.b.1)a), and I incorporate that discussion here as if set forth fully herein. I have not repeated them solely for the sake of brevity.

529. In addition, Mr. Anderson suggests that the skilled person would have had a reason

to combine the dose counter of the '021 Publication with the canister housing of the '514 Publication, and that this combination would have resulted in the invention of Asserted Claim 1. I disagree for several reasons.

530. The POSA would not have viewed the dose counter of the '021 Publication as compatible with the design of the actuator of the '514 Publication. The '514 Publication emphasizes the importance of affixing its dose indicator to the medication canister, such that neither is movable relative to the other—fundamentally, the '514 Publication is directed to an annular dose indicator, not canister housing design. The dose counters disclosed in the '021 Publication are not affixed to the canister, but rather the canister moves toward and away from the dose counter of the '021 Publication as the POSA actuates the device. Accordingly, the POSA would not have reason to combine one of the dose counters disclosed in the '021 Publication with the inhaler bodies disclosed in the '514 Publication, nor would the POSA reasonably have expected success in doing so. To the contrary, the POSA would have expected that combining a housing designed to accommodate an annular dose counter affixed to the canister with a different dose counter located substantially below the canister would have been unsuccessful, if not inoperable. As the POSA would have understood, inhaler components must be tailored to work with a given dose counter, and dose counter components must be tailored to work with a given canister housing, valve, etc. As the '514 Publication explains, the POSA would have expected that the body of the inhalers disclosed in the '514 Publication would not have accommodated the dose counter of the '021 Publication, since locating the dose counter below the canister often requires “modification of adaptor geometry.” '514 Publication, 3:5-10.

531. In addition, the POSA would have understood that the close fit between the annular dose counter affixed to the canister and the canister housing acted to stabilize the canister within

the canister housing. Accordingly, the POSA would have expected the canister housing of the '514 Publication to be unsuitable for any design that did not stabilize the canister in this manner. The POSA therefore would not have had a reasonable expectation of success in achieving a robust and accurate inhaler/dose counting system by combining the canister housing disclosed in the '514 Publication with a dose counter, like the ones disclosed in the '021 Publication, that was not affixed to the canister and could not be expected to stabilize it within the canister housing accordingly.

532. Furthermore, the POSA would not have reasonably expected success in combining inhaler bodies of the '514 Publication with the dose counter of the '021 Publication because the inhaler bodies of the '514 Publication contain an "actuation pin" that is configured to be "received within the dose indicator, e.g. passing through a cut-out portion (66) in the second edge (62) of the housing (see Figure 5)." '514 Publication, 25:24-27. The POSA would have understood that such a pin would have been structurally incompatible with the dose counters disclosed in the '021 Publication. The POSA would have expected "actuation pin (29)" to physically prevent insertion of the dose counters disclosed in the '021 Publication appropriately into the canister housing.

533. Furthermore, the '514 Publication discloses numerous housings, many of which do not have support rails, *see, e.g.*, '514 Publication, Figures 2b, 3, 8b, 10, and 12a, and it mentions support rails only once in its entire disclosure as an optional feature of the housing, unrelated to the dose indicator the '514 Publication devotes the remainder of its disclosure to describing, *see* '514 Publication, 17-19. Thus, the POSA would not have had reason to (1) select one of the embodiments in the '514 Publication that discloses support rails, and then (2) modify that embodiment by eliminating the feature that is the primary subject of the '514 Publication's disclosure (its annular dose indicator), and then (3) integrate a dramatically different dose counter (such as that of the '021 Publication, which is affixed to the canister housing and is not affixed to

the medication canister) into the canister housing of the '514 Publication. To the contrary, the POSA would not have expected such a combination to be operable, let alone successful.

534. Even were the POSA to have combined the dose counter of the '021 Publication with the canister housing of the '514 Publication, that combination would not have resulted in the claimed invention. There would have been many ways to align the actuation member of the dose counters of the '021 Publication with the optional inner wall canister support formations of the '514 Publication's canister housing, and the POSA would have had no reason to select an alignment that satisfies the Common Plane Limitation. To the contrary, neither the '021 Publication nor the '514 Publication suggested the importance of aligning support rails with any aspect of a dose counter or indicator, nor did they disclose the need to minimize canister rocking in connection with the addition of a dose counter, let alone suggest the use of canister support rails to do so. Indeed, the POSA would not have expected the devices disclosed in the '514 Publication to experience problems of the canister rocking in connection with the dose indicator, because the canister and dose indicator were affixed together. Nor would the POSA have expected the devices disclosed in the '021 Publication to experience such problems, since the actuation member(s) of the dose counter of the '021 Publication would have been expected to contact the medication canister symmetrically.

b) Claim 2

535. Asserted Claim 2 depends from Asserted Claim 1 and recites: "The inhaler as claimed in claim 1 wherein the medicament canister is moveable relative to the dose counter." In my opinion, at a minimum, the "inhaler as claimed in claim 1" would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.1)b). Thus, Asserted Claim 2 would not have been obvious to the POSA in light of the '021 Publication.

c) Claim 3

536. Asserted Claim 3 of the '289 Patent depends from Asserted Claim 1 and recites: "The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." In my opinion, at a minimum, the "inhaler as claimed in claim 1" would not have been obvious to the POSA in light of the '021 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.1)a). Thus, Asserted Claim 3 would not have been obvious to the POSA in light of the '021 Publication.

d) Claim 4

537. Asserted Claim 4 of the '289 Patent depends from Asserted Claim 1 of the '289 Patent and recites: "The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 1" would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.1)b). Thus, Asserted Claim 4 would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication.

e) Claim 5

538. Asserted Claim 5 of the '289 Patent depends from Asserted Claim 4 of the '289 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the "inhaler as claimed in claim 4" would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.1)d). Thus, Asserted Claim 5 would not have been obvious to the POSA in light of the '021 Publication.

f) Claim 6

539. Asserted Claim 6 of the '289 Patent depends from Asserted Claim 4 of the '289

Patent and recites: “The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the “inhaler as claimed in claim 4” would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.1)d). Thus, Asserted Claim 6 would not have been obvious to the POSA in light of the ’021 Publication.

g) Claim 7

540. Asserted Claim 7 of the ’289 Patent depends from Asserted Claim 6 of the ’289 Patent and recites: “The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other.” In my opinion, at a minimum, the “inhaler as claimed in claim 6” would not have been obvious to the POSA in in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.1)f). Thus, Asserted Claim 7 would not have been obvious to the POSA in light of the ’021 Publication.

h) Claim 8

541. Asserted Claim 8 of the ’289 Patent depends from Asserted Claim 4 of the ’289 Patent and recites: “The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.” .In my opinion, at a minimum, the “inhaler as claimed in claim 4” would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.1)d). Thus, Asserted Claim 8 would not have been obvious to the POSA in light of the ’021 Publication.

2) The ’587 Patent

542. Mr. Anderson argues that the ’514 Publication in combination with the ’021

Publication renders obvious Asserted Claims of the '587 patent. I disagree, and I incorporate by reference my analysis of the '514 Publication in Section IV.A and my analysis of the '021 Publication in Section IV.D as though fully set forth herein. I have not reproduced those sections here solely for the sake of brevity.

a) Claim 1

543. As I explain above, Asserted Claim 1 of the '587 Patent is materially identical to Claim 1 of the '289 Patent, except that Asserted Claim 1 of the '587 Patent adds the additional limitation that “the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

544. Because Asserted Claim 1 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that Asserted Claim 1 of the '587 Patent would not have been obvious in light of the '021 Publication in combination with the '514 Publication.

545. Furthermore, the '021 Publication fails to disclose or otherwise suggest the arrangement of an inner wall canister support formation such that it protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.”

546. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the '021 Publication because the '021 Publication “discloses every structural element” of the claim and these structural elements necessarily “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” *See* Anderson Opening Rep. ¶ 299.

547. I disagree as a factual matter that this language is meaningless—it requires a result

(protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler) that the '587 Patent does not require.

548. Regardless, I disagree that the '021 Publication discloses, or renders obvious, every structural element of the claim—as I described above, the '021 Publication fails to disclose several limitations of Asserted Claim 1.

549. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation.

550. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



551. Despite the visible presence of support rails (i.e., inner wall canister formations), it

is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

552. Accordingly, even if the POSA had reason to modify the disclosure of the '021 Publication by transferring the dose counter it discloses into a canister housing that includes an inner wall canister support formation (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the '587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the

'021 Publication in the manner Mr. Anderson suggests.

b) Claim 2

553. Asserted claim 2 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter." In my opinion, at a minimum, the "inhaler as claimed in claim 1" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 2 of the '289 Patent, which contains the same additional limitation as Asserted Claim 2 of the '587 Patent.

c) Claim 3

554. Asserted Claim 3 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." In my opinion, at a minimum, the "inhaler as claimed in claim 1" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 3 of the '289 Patent, which contains the same

additional limitation as Asserted Claim 3 of the '587 Patent.

d) Claim 4

555. Asserted Claim 4 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1, first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 1" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)a). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)a) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 4 of the '289 Patent, which contains the same additional limitation as Asserted Claim 4 of the '587 Patent.

e) Claim 5

556. Asserted Claim 5 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, at a minimum, the "inhaler as claimed in claim 4" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 5 of the '289 Patent, which contains the same additional limitation as Asserted Claim 5 of

the '587 Patent.

f) Claim 6

557. Asserted Claim 6 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the '289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

g) Claim 7

558. Asserted Claim 7 of the '587 Patent depends from Asserted Claim 6 of the '587 Patent and recites: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main the body to face each other." In my opinion, at a minimum, the "inhaler as claimed in claim 6" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)f). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)f) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 7 of the

'289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

h) Claim 8

559. Asserted Claim 8 of the '587 Patent depends from Asserted Claim 4 of the '587 Patent and recites: "The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." In my opinion, at a minimum, the "inhaler as claimed in claim 4" of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)d). Accordingly, this claim would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. I incorporate all of my analysis as set forth in Section VI.A.2.d.2)d) above into this Section, as if set forth fully herein. I have not repeated my analysis here solely for the sake of brevity. I also incorporate by reference as though set forth fully herein my analysis of Asserted Claim 6 of the '289 Patent, which contains the same additional limitation as Asserted Claim 6 of the '587 Patent.

i) Claim 11

560. Asserted Claim 11 of the '587 Patent depends from Asserted Claim 1 of the '587 Patent and recites: "The inhaler as claimed in claim 1, further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X."

561. In my opinion, at a minimum, the dose counter claimed in Asserted Claim 1 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)a). Thus, Asserted Claim 11 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication.

562. In addition, as I explained above, the '021 Publication does not disclose an inner wall canister support formation, and therefore does not disclose Asserted Claim 11's requirement for a "second inner wall canister support formation," let alone a configuration "wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with longitudinal axis X." For all the reasons I described above with respect to Asserted Claim 1, the POSA would not have had a reason to alter the disclosure of the '021 Publication by removing its dose counter from the disclosed housing and adding that dose counter to a housing containing multiple inner wall canister support formations. Indeed, the POSA would have resisted this more dramatic change to the canister housing of the '021 Publication would have exacerbated the concerns regarding changes to airflow and product performance that I explained above.

j) Claim 12

563. Asserted Claim 12 of the '587 Patent is materially identical to Asserted Claim 1 of the '289 Patent, except that Asserted Claim 12 of the '587 Patent adds the additional limitation "such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member."

564. Because Asserted Claim 12 of the '587 Patent contains every limitation of Asserted Claim 1 of the '289 Patent, I conclude for the reasons I described above that Asserted Claim 12 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication.

565. In addition, the '514 Publication in combination with the '021 Publication fails to render obvious Asserted Claim 12 of the '587 Patent because neither Publication discloses or otherwise suggest an inhaler configuration "such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away

from the actuation member.”

566. Mr. Anderson suggests that this limitation is either meaningless or that it is “inherently” disclosed by the ’021 Publication because the ’021 Publication “discloses every structural element” of the claim and these structural elements necessarily protect against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member. Anderson Opening Rep. ¶ 299.

567. I disagree as a factual matter that this language is meaningless—it requires a result (protecting against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member) that the ’289 Patent does not require.

568. Regardless, I disagree that the combination of the ’514 Publication and the ’021 Publication “discloses every structural element” of the claim—as I described above, these references not disclose the Common Plane Limitation either alone or in combination.

569. I also disagree that the mere presence of an inner wall canister support formation that lies in a common plane with the central outlet port and the actuation member of the dose counter is sufficient to establish that the arrangement will “protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member.” While the POSA would have been able, based on the teachings of the Asserted Patents, to achieve this result without undue experimentation, not every support rail, inhaler, and canister combination that satisfied the common plane limitation would do so. Indeed, as my infringement reports reflect, I conducted experiments to determine empirically whether Defendants’ products meet this limitation.

570. My opinion is further supported by the GlaxoSmithKline product Flixotide, the canister housing of which I have shown below:



571. Despite the visible presence of support rails (i.e., inner wall canister formations), it is nonetheless possible to press on the canister of Flixotide (i.e., rocking it toward the canister housing) in a manner that will empty the entire canister even though the canister has never been depressed in the manner a patient would use in order to take a dose of medication. This design flaw demonstrates that the mere presence of support rails in a given canister housing is not sufficient to reduce undesirable canister rocking. Indeed, while no dose counter (and thus no actuation member) is visible in this image and therefore it is not possible to evaluate whether any support rail lies in a common plane with an actuation member, it is plain that the given assembly of support rails permits unacceptable canister rocking. It also illustrates the need to precisely tailor inhaler components to one another—the flexibility of the valve stem in Flixotide also contributes to this disadvantageous phenomenon.

572. Mr. Anderson does not separately address Asserted Claim 12 in his analysis, instead conflating its final limitation with the final limitation of Asserted Claim 1. That is incorrect. Reducing rocking of the canister with respect to the main body of the inhaler is not the same as reducing rocking of the canister towards or away from the actuation member. To the contrary, the POSA would have understood that certain support rail configurations could achieve the former but not the latter. Nothing in the '514 Publication or the '021 Publication (alone or in combination)

discloses an inner wall canister support formation that prevents rocking of the canister towards or away from the actuation member.

573. Accordingly, even if the POSA had reason to modify the disclosure of the '021 Publication by transferring the dose counter it discloses into an inhaler of the '514 Publication (and for the reasons described above, the POSA would not have done so), I do not agree that the resulting configuration would necessarily have “protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister towards or away from the actuation member” as Asserted Claim 1 of the '587 Patent requires. Mr. Anderson has identified no disclosure in *any* prior art reference that identifies the problem solved by Asserted Claim 1 of the '587 Patent (namely, rocking of the canister as a result of interaction with the dose counter). Nor does Mr. Anderson identify any disclosure in any prior art reference that specifically discloses the location of the inner wall canister support formation relative to a component of the dose counter—let alone a reference that suggests such elements should be arranged in a common plane to reduce canister rocking and improve dose counter accuracy. Accordingly, the POSA would have had no reason to modify any embodiment disclosed in the '021 Publication in the manner Mr. Anderson suggests.

k) Claim 13

574. Asserted Claim 13 recites:

13. An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a medicament canister retained in the canister housing and movable relative thereto,
and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, wherein the canister housing has

an aperture formed in the inner wall through which the portion of the actuation member extends, and wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

575. As I described above with respect to Asserted Claim 1, the '021 Publication fails to disclose an "inner wall canister support formation" and the POSA would not have had reason to modify any device disclosed in the '021 Publication by transferring the dose counter in that device to a canister housing of the '514 publication. I incorporate that analysis herein, and therefore conclude that Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication.

l) Claim 14

576. Asserted Claim 14 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the medicament canister is moveable relative to the dose counter." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)k). Thus, Asserted Claim 14 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '514 Publication in combination with the '021 Publication.

577. In addition, the combination of the '514 Publication and the '021 Publication fails to render obvious Asserted Claim 14's dependent limitation, for the reasons I addressed in Section VI.A.2.d.1)b), with respect to the same limitation in the context of Asserted Claim 2 of the '289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

m) Claim 15

578. Asserted Claim 15 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the first inner wall canister support formation

comprises a support rail which extends longitudinally along an inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.2)k). Thus, Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication.

579. In addition, the combination of the ’514 Publication and the ’021 Publication fails to render obvious Asserted Claim 15’s dependent limitation, for the reasons I addressed in Section VI.A.2.d.1)d), with respect to the same limitation in the context of Asserted Claim 4 of the ’289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

n) Claim 16

580. Asserted Claim 16 of the ’587 Patent depends from Claim 15 and recites: “The inhaler as claimed in claim 15, wherein the support rail includes a step formed thereon.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.2)m). Thus, Asserted Claim 16 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication.

581. In addition, the combination of the ’514 Publication with the ’021 Publication fails to render obvious Asserted Claim 16’s dependent limitation, for the reasons I addressed in Section VI.A.2.d.1)e), with respect to the same limitation in the context of Asserted Claim 5 of the ’289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

o) Claim 17

582. Asserted Claim 17 of the ’587 Patent depends from Asserted Claim 15 and recites:

“The inhaler as claimed in claim 15 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.2)m). Thus, Asserted Claim 17 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication.

583. In addition, the ’514 Publication in combination with the ’021 Publication fails to render obvious Asserted Claim 17’s dependent limitation, for the reasons I addressed in Section VI.A.2.d.1)f) with respect to the same limitation in the context of Asserted Claim 6 of the ’289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

p) Claim 18

584. Asserted Claim 18 of the ’587 Patent depends from Claim 17 and recites: “The inhaler as claimed in claim 17, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 17 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.2)o). Thus, Asserted Claim 18 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication.

585. In addition, the ’514 Publication in combination with the ’021 Publication fails to render obvious Asserted Claim 18’s dependent limitation, for the reasons I addressed in Section VI.A.2.d.1)g), with respect to the same limitation in the context of Asserted Claim 7 of the ’289 Patent. I incorporate that analysis by reference here as though fully set forth herein.

q) Claim 19

586. Asserted Claim 19 of the ’587 Patent depends from Asserted Claim 15 and recites:

“The inhaler as claimed in claim 15, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along the inside surface of the main body.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.2)m). Thus, Asserted Claim 19 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication.

587. In addition, the ’514 Publication in combination with the ’021 Publication fails to render obvious Asserted Claim 19’s dependent limitation, for the reasons I addressed in Section VI.A.2.d.1)h), with respect to the same limitation in the context of Asserted Claim 8 of the ’289 Patent. I incorporate that analysis by reference here.

r) Claim 20

588. Asserted Claim 20 of the ’587 Patent depends from Asserted Claim 15 and recites: “The inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” In my opinion, at a minimum, the dose counter claimed in Asserted Claim 15 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication. *See supra* Section VI.A.2.d.2)m). Thus, Asserted Claim 19 of the ’587 Patent would not have been obvious to the POSA in light of the ’514 Publication in combination with the ’021 Publication.

589. In addition, the ’021 Publication fails to render obvious the limitation “wherein a width dimension of the support rail is not constant and the width dimension is greatest at the location where the support rail is closest to the aperture.” The ’021 Publication fails to disclose or render obvious the inclusion of *any* inner wall canister support formation, let alone one with the

particular characteristics claimed in Asserted Claim 20. The '514 Publication simply never reports the dimensions of its support rails, nor is it apparent where in the inhaler bodies of the '514 Publication the dose counters of the '021 publication would rest, and therefore it is not apparent whether the width dimension of the support rail would be greatest "at the location where the support rail is closest to the aperture."

s) Claim 21

590. Asserted Claim 21 of the '587 Patent depends from Asserted Claim 13 and recites: "The inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 13 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)k). Thus, Asserted Claim 21 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication.

591. In addition, the combination of the '514 Publication and '021 Publication fails to render obvious the "wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fires stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." Since the aperture of Asserted Claim 21 is the aperture through which the actuation member of the dose counter extends, the aperture of Asserted Claim 21 is located in the same place as the actuation member. As I described above with respect to Asserted Claim 1 of the '289 Patent, which analysis I incorporate by reference as though fully set forth herein, the '514 Publication in combination with the '021 Publication does not render

obvious an inhaler in which the actuation member, center of the central outlet port, and an inner wall canister support formation lie in a common plane. I incorporate that analysis here by reference.

t) Claim 22

592. Asserted Claim 22 of the '587 Patent depends from Asserted Claim 21 of the '587 Patent and recites: "The inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X." In my opinion, at a minimum, the dose counter claimed in Asserted Claim 21 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication. *See supra* Section VI.A.2.d.2)s). Thus, Asserted Claim 22 of the '587 Patent would not have been obvious to the POSA in light of the '514 Publication in combination with the '021 Publication.

593. In addition, the combination of the '514 Publication with the '021 Publication fails to render obvious the limitation of Asserted Claim 22 requiring "a second inner wall canister support formation" and the limitation requiring that "the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X." I addressed these limitations in the context of Asserted Claim 11 of the '587 Patent above, and I incorporate that analysis by reference here.

* * *

594. In sum, I disagree with Mr. Anderson's conclusions that the Asserted Claims would have been obvious, including based on the references and supposed knowledge that he describes in his reports. However, even if Mr. Anderson could show that the Asserted Claims would have

been obvious in view of those arguments, in my opinion, strong objective indicia of non-obviousness establish that the claims are not invalid. *See* Lewis Opening Reps. § IX.

595. I further note that the '514 and '021 Publications were before the examiner during prosecution of the '289 and '587 Patents. *See, e.g.,* '289 Patent, U.S. Patent Documents, Foreign Patent Documents; '587 Patent, U.S. Patent Documents, Foreign Patent Documents. I have conducted an independent analysis of the '514 and '021 Publications, and in my opinion, the '514 and '021 Publications do not render obvious the Asserted Claims, alone or in combination with the other references and purported knowledge that Mr. Anderson describes. The fact that the examiner made similar determinations as to each of these claims provides further evidence that the '514 and '021 Publications do not render obvious those claims.

B. The '156 Patent

1. Mr. Anderson's Anticipation Theories Are Incorrect

a. The '021 Publication Does Not Anticipate the Asserted Claims of the '156 Patent

596. Mr. Anderson opines that the '021 Publication anticipates Asserted Claims 1, 9, and 11-13 the '156 Patent. *See* Anderson Opening Rep. § XVI.A. I disagree. In my opinion, the POSA would not understand the '021 Publication to disclose the limitations of the Asserted Claims as arranged in those claims. I incorporate by reference my analysis of the '021 Publication in Section IV.D as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

597. Asserted Claim 1 recites as follows:

1. A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
a ratchet wheel having a plurality of circumferentially

spaced teeth,
an actuator comprising an actuator pawl arranged to
engage with a first tooth of the ratchet wheel, wherein the
actuator can be driven in
response to canister motion to drive the ratchet wheel to
rotate,
a count pawl arranged to engage with a second tooth of
the ratchet wheel, wherein as the ratchet wheel is driven by
the actuator to rotate,
the count pawl rides along a forward surface of the second
tooth and resiliently jumps
over the second tooth, and
a dosage indicator associated with the count pawl,
wherein the actuator is arranged to define a first reset
position in which the actuator pawl is brought into
engagement with the first tooth,
wherein the actuator is further arranged such that, during
a canister fire sequence, when the actuator is in a
second position, which is after the first reset position and at a
canister fire configuration,
the medicament canister fires medicament before the dose
counter reaches a count
configuration, and when the actuator is in a third position
after the second position, the
count pawl resiliently jumps over the second tooth and the
dose counter reaches the count
configuration, whereby the dosage indicator has indicated a
count,
wherein, in the canister fire configuration, the actuator
pawl is below a datum plane which passes through a shoulder
of a valve stem block
configured to receive the medicament canister.

Asserted Claims 9 and 11-13 depend, directly or indirectly, from Asserted Claim 1.

598. I have been informed that the parties have agreed upon constructions for the terms “body,” “associated with,” “actuator,” “actuator pawl arranged to engage with a first tooth of the ratchet wheel,” “wall surfaces separating the canister receiving portion and the counter chamber,” and “ratchet wheel.” *See supra* Section III.B. I have applied those constructions in performing my analysis.

599. I further have been informed that the parties have proposed different constructions

for the terms “canister fire sequence,” “first reset position,” “canister fire configuration,” “count configuration,” “datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister,” and “count pawl.”

<u>No.</u>	<u>Claim Term</u>	<u>Teva’s Construction</u>	<u>Defendants’ Construction</u>
5	“first reset position” ’156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration”	“configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel”
6	“canister fire sequence” ’156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament”	“process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel.”
7	“canister fire configuration”	Plain and ordinary meaning in view of the claims,	“configuration in which the actuator pawl is lower than in the first reset position and below the datum plane

<u>No.</u>	<u>Claim Term</u>	<u>Teva's Construction</u>	<u>Defendants' Construction</u>
	'156 Patent, claims 1, 2	specification, and prosecution history. “a configuration of the dose counter in which the medicament canister fires medicament”	and the medicament is ejected”
8	“count configuration” '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a configuration of the dose counter whereby the dosage indicator has indicated a count”	“configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose”
9	“datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister” '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister”	“plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet”
16	“count pawl” '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the ratchet wheel”	“a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel”

600. I have not been asked to provide an opinion as to which proposed constructions are

correct, and I express no opinion on that issue. In my opinion, the '021 Publication does not anticipate any Asserted Claim of the '156 Patent under any proposed construction.

1) The '021 Publication Does Not Disclose the Limitations of the Asserted Claims as Arranged in Those Claims

601. As an initial matter, in my opinion, the '021 Publication does not anticipate any Asserted Claim of the '156 Patent because the '021 Publication does not disclose the limitations of the Asserted Claims as arranged in those claims. Notably, Mr. Anderson does not opine that any single disclosure within the '021 Publication discloses every limitation of any Asserted Claim. Instead, as to each of the Asserted Claims, Mr. Anderson relies on a select number of disparate descriptions and figures in the '021 Publication. *See, e.g.*, Anderson Opening Rep. § XVI.A (citing '021 Publication, Abstract; Paragraphs [0002], [0076], [0088], [0091], [0101], [0104]; Figs. 1-12, 21, 24, 39-41, 48). Mr. Anderson offers no explanation as to why the POSA would focus on that specific selection of descriptions and figures as opposed to any others in the publication.

602. In my opinion, the POSA would not have focused on the selection of descriptions and figures that Mr. Anderson relies upon or treated them as a single disclosure or embodiment. As the '021 Publication makes clear, those descriptions and figures relate to different, “alternative embodiments” of the purported invention(s). *See, e.g.*, '021 Publication, ¶¶ [0024]-[0035], [0047], [0062]-[0064], [0071]. The '021 Publication further makes clear that, within these “embodiments,” the invention(s) can be configured to comprise a variety of components, each of which can be configured in a variety of shapes and sizes.” *See, e.g.*, '021 Publication, ¶¶ [0076] (“It should be understood that the container can be configured in a variety of shapes and sizes, and that the substance contained therein can be released by any number of valve systems that are well known in the art. It should also be understood that the valve system can be actuated by a variety of actuators, including, but not limited to, various pumps, levers, actuator hoots, buttons and the

like.”); [0096] (“The indicator wheel 58, indicia 66 and viewing window 28 can be arranged in a variety of configurations for viewing by the user.”).

603. The ’021 Publication does not provide a reason why the POSA would have focused on the disparate elements of those disparate embodiments or treated them as a single disclosure or embodiment, and the POSA would not have had a reason to do so. For example, the ’021 Publication describes Figures 7 and 12, as depicting different “alternative embodiments” of the “indicator module”; and describes Figures 40, 41, and 48, as depicting other components. *See, e.g.,* ’021 Publication ¶¶ [30], [35], [64], [65], [71]. Thus, as I explain below, the POSA would not have viewed those figures as depicting the devices that Mr. Anderson opines to be anticipated. *See infra* Section VI.B.1.a.1). Mr. Anderson’s selective reliance on elements across embodiments provides further evidence that his analysis is based on a hindsight-driven effort to reconstruct the inventions recited in the Asserted Claims rather than a genuine effort to understand how the POSA would have understood the prior art.

1) Claim 1

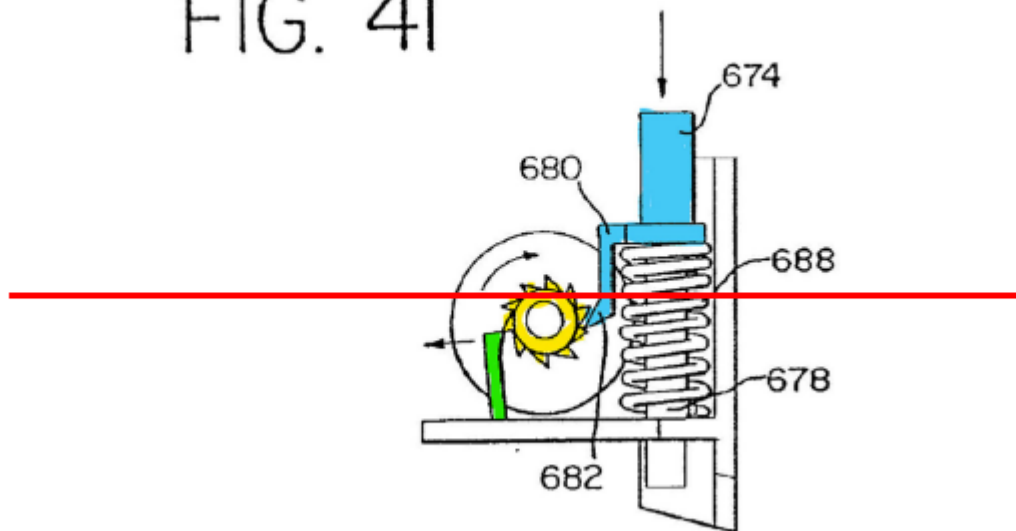
a) The ’021 Publication Does Not Disclose Firing Before Counting

604. Additionally, in my opinion, the ’021 Publication does not anticipate Asserted Claim 1 of the ’156 Patent (and, therefore, does not anticipate any Asserted Claim) because it does not disclose the limitation “wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.”

605. Under both sides' proposed constructions, Asserted Claim 1 requires the "actuator" to be "arranged such that" the device reaches a "canister fire configuration," in which "the medicament canister fires medicament before the dose counter reaches a count configuration," "whereby the dosage indicator has indicated a count." That is, under both sides' proposed constructions, the "canister fire configuration" must occur before the "count configuration."

606. Mr. Anderson opines that the '021 Publication discloses a device in which the "canister fire configuration" occurs before the "count configuration" (which he addresses in discussing what he terms Limitation 1F) based on a flawed analysis of Figure 41 of the '021 Publication. I reproduce Mr. Anderson's marked-up version of Figure 41 below.

FIG. 41



Anderson Opening Rep. ¶ 340. According to Mr. Anderson, "Figure 41 depicts the dose counter disclosed in the '021 Publication in the fire configuration, during a downward stroke, just before a count has been indicated (as evidenced by the fact that the count pawl is just about to jump over the second tooth of the ratchet wheel)." Anderson Opening Rep. ¶ 342. In my opinion, Mr. Anderson's analysis suffers from multiple flaws.

607. First, the '021 Publication does not support Mr. Anderson's assertion that Figure 41 depicts a dose counter in the "canister fire configuration." The '021 Publication does not mention the phrase "canister fire configuration" or the like, and the POSA would not be able to infer from the '021 Publication's disclosures when the device depicted in Figure 41 fires relative to when the dose indicating mechanism counts. Indeed, the '021 Publication's discussion of Figure 41 is not intended to provide any information about the timing of when the device fires. The '021 Publication explains that Figure 41 depicts the operation of the dose indicating mechanism, not the firing mechanism, and does not purport to depict the dose indicating mechanism at any particular point in a canister firing sequence. *See, e.g.*, '021 Publication, [0064] ("FIG. 41 is a side view of the actuator member engaging the first indicator member with the non-return being biased outwardly."); [0104]-[0107]. Nor would the POSA be able to infer any such information based on Figure 41, which presents a planar, two-dimensional depiction of the dose indicating mechanism in isolation. To the contrary, the POSA would understand that the "canister fire configuration" could occur at numerous points during the dose indicating mechanism's operation, and that those points might vary depending on, for example, the sizes and shapes of any valve stems and valve stem blocks used in combination with the dose indicating mechanism. The '021 Publication does not specify any such parameters for the components depicted in Figure 41.

608. Second, and relatedly, even assuming, contrary to my opinion, that Figure 41 depicts a dose counter in the "canister fire configuration," neither Figure 41 nor anything else in the '021 Publication discloses a device in which the "canister fire configuration" occurs before the "count configuration." Thus, this limitation is wholly absent from the '021 Publication, and the '021 Publication does not anticipate the claim.

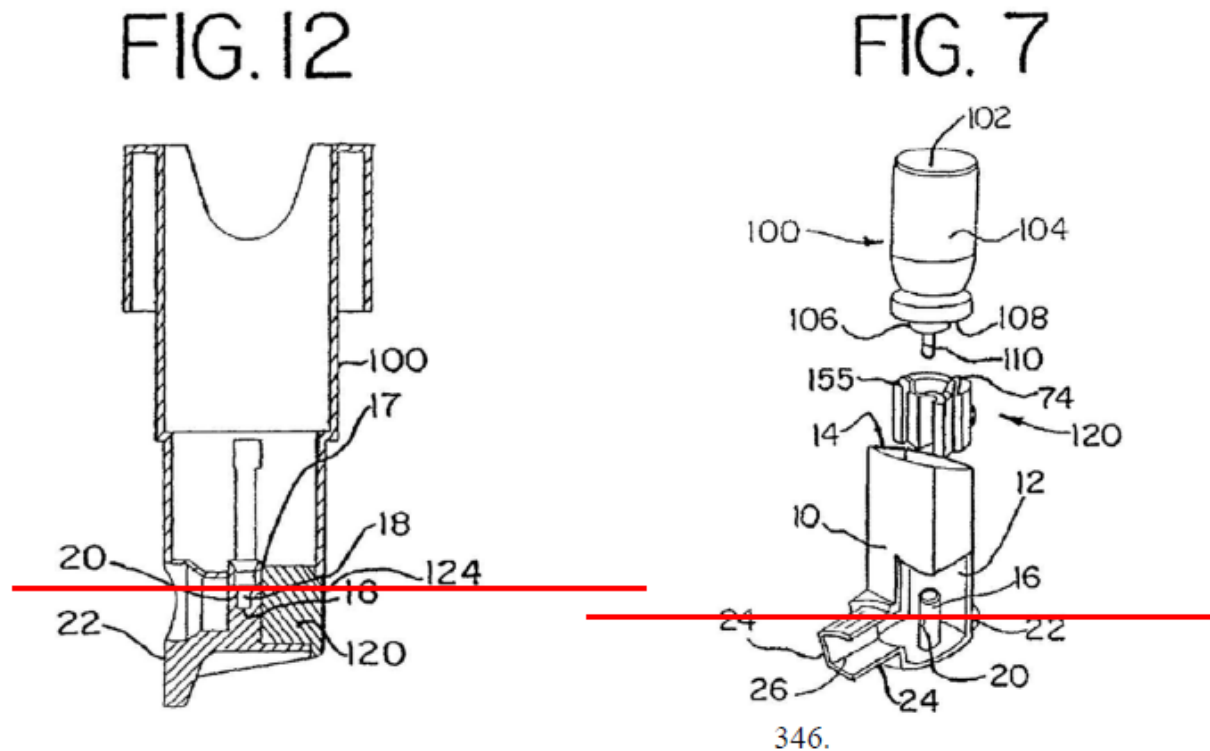
609. Mr. Anderson does not articulate any theory that Figure 41 somehow inherently

discloses that the “canister fire configuration” occurs before the “count configuration.” Nor could he. I have been informed that for a reference to inherently disclose a limitation such a limitation must be necessarily present in or naturally result from the disclosed embodiment. But, the embodiment depicted in Figure 41 does not necessarily or naturally fire before counting. To the contrary, and because the ’021 Publication does not indicate the opposite, the POSA would expect that the devices disclosed in the ’021 Publication count *before* firing given FDA guidance that devices “should be designed to specifically avoid undercounting.” *See, e.g.*, FDA Guidance 2003, TEVAQVAR-00032577-78; *infra* Section VI.B.2.a.2)a); Stein at 334.

b) The ’021 Publication Does Not Disclose an “Actuator Pawl” Below the “Datum Plane” in the “Canister Fire Configuration”

610. Additionally, in my opinion, the ’021 Publication does not anticipate Asserted Claim 1 of the ’156 Patent (and, therefore, does not anticipate any Asserted Claim) because it does not disclose the limitation “wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.”

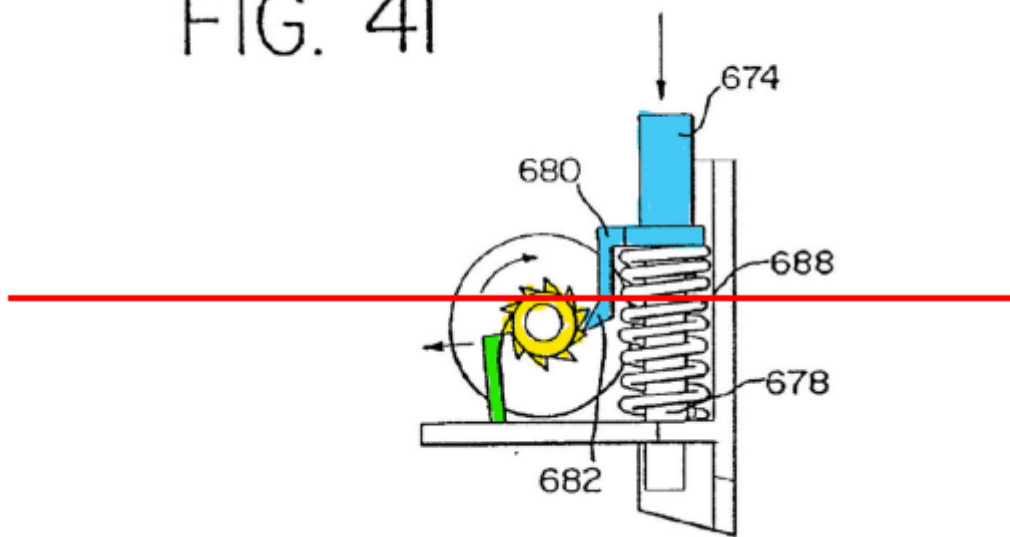
611. To support his contrary opinion, Mr. Anderson offers a flawed analysis of Figures 12 and 7 of the ’021 Publication (in connection with what he terms Limitation 1G). I reproduce Mr. Anderson’s marked-up versions of Figures 12 and 7 below.



612. Anderson Opening Rep. ¶ 345. In discussing Figures 12 and 7, Mr. Anderson asserts: “Figure 7 of the ’021 Publication discloses how the dose counter chamber 120 can be inserted into a canister housing. Figure 12 shows the interior of the valve stem. In Figures 12 and 7, orifice 20 depicts where medicament is expelled from the valve stem. Thus, under either Party’s construction, the datum plane line must be placed at this orifice, as no other potential “shoulder” structure, exists. *See Fig. 12.*” Anderson Opening Rep. ¶ 345.

613. Although Mr. Anderson’s reasoning is not clear, Mr. Anderson appears to extrapolate from his analyses of Figures 12 and 7 to depict the location of the datum plane in certain other figures of the ’021 Publication, including Figure 41, which he mistakenly associates with the “canister fire configuration.”

FIG. 4I



Anderson Opening Rep. ¶ 340. Again, in my opinion, Mr. Anderson's analysis suffers from multiple flaws.

614. First, Mr. Anderson's assertion that Figures 12 and 7 disclose a "shoulder" located at orifice 20 is unsupported. Looking at Figures 12 and 7, the POSA would be unable to locate the datum plane. Thus, Mr. Anderson is forced to resort to conjecture as to where the "datum plane passing through a shoulder of the valve stem block" is located in those figures. Thus, at this first step, Mr. Anderson's theory fails. I have been informed that anticipation is based on the POSA's reading of the prior art reference. The POSA would not be able to locate the datum plane on those indicated figures, and thus the '021 Publication does not disclose this limitation.

615. Lacking any basis in the figures, Mr. Anderson assumes, without reason, that because the medicament exits from the valve stem block at orifice 20, a shoulder "must be placed" at that location. Contrary to Mr. Anderson's assertion, however, the location of the orifice through which medicament exits from the valve stem block has no relationship to the location of any shoulder within the valve stem block. A given valve stem block might contain no shoulder at all,

and even assuming, contrary to my opinion, that it did, such a shoulder could be located above or below the orifice through which medicament exits.

616. Second, even assuming, contrary to my opinion, that Figures 12 and 7 disclose a shoulder at orifice 20, Mr. Anderson's reliance on Figures 12 and 7 to extrapolate the location of the datum plane in other, disparate figures, including Figure 41, is without basis. Simply put, nothing in Figures 12 or 7 depicts the dose indicating mechanism; thus, they do not depict where in the dose indicating mechanism the datum plane as drawn by Mr. Anderson would fall. And nothing in Figure 41 depicts a valve stem block, much less a "shoulder" of a valve stem block, such that a datum plane could be placed. I cannot determine how Mr. Anderson made his flawed extrapolations, but see no basis to support it. Indeed, a comparison of Mr. Anderson's marked-up figures illustrates that even Mr. Anderson's efforts to place the datum plane do not appear to be internally consistent because, across those embodiments, he places the datum plane at different heights relative to the valve stem.

617. In addition, and as I explain above, the '021 Publication makes clear that its various descriptions and figures refer to different, "alternative embodiments" of the purported invention(s), *see, e.g.*, '021 Publication, ¶¶ [0024]-[0035], [0047], [0062]-[0064], [0071], and that within these embodiments, the invention(s) can be configured to comprise a variety of components, each of which can be configured in a variety of shapes and sizes, *see, e.g.*, '021 Publication, ¶¶ [0076], [0096]. Thus, the POSA would not understand that the location of a particular component in one embodiment (e.g., as shown in Figures 12 and 7) could be extrapolated to determine the existence or location of a corresponding component in a different embodiment (e.g., as shown in Figure 41). Thus, as relevant here, the POSA would not understand embodiments described and/or depicted in figures other than Figures 12 and 7 would comprise an orifice 20 or similar orifice in the same

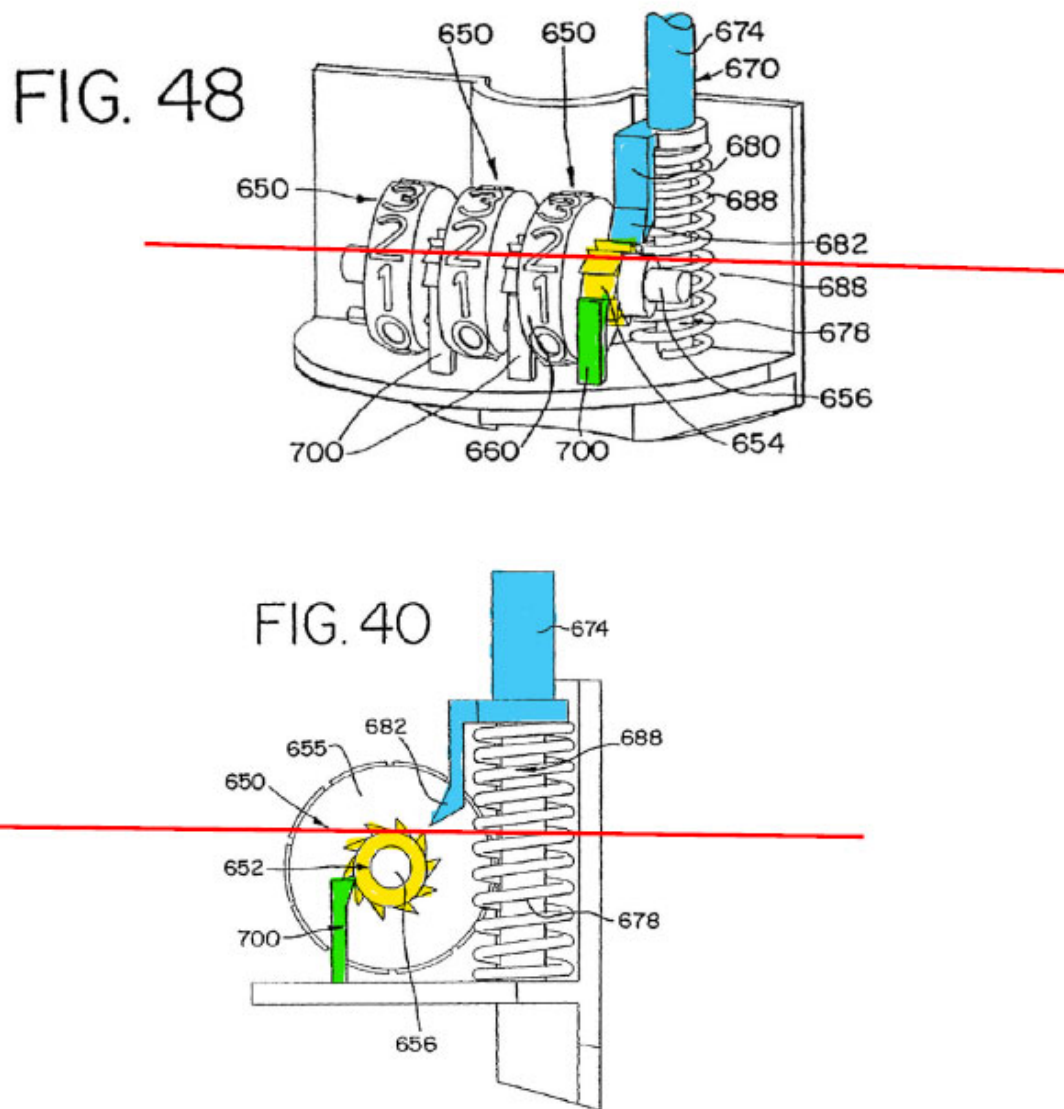
or similar location.

618. Third, as I explain above, the '021 Publication does not support Mr. Anderson's assertion that Figure 41 depicts the device in the "canister fire configuration." *See supra* Section VI.B.1.a.1)a). Thus, Mr. Anderson's analysis fails in any event.

**c) The '021 Publication Does Not Disclose a
"Canister Fire Sequence," a "First Reset
Position" or a "Count Configuration" Under
Defendants' Proposed Constructions**

619. Additionally, in my opinion, the '021 Publication does not anticipate Asserted Claim 1 of the '156 Patent (and, therefore, does not anticipate any Asserted Claim of the '156 Patent) under Defendants' proposed constructions of the terms "canister fire sequence," "first reset position," and "count configuration." As shown in the table above, Defendants' proposed constructions for those terms require the "actuator pawl" to have a specific location relative to the above-mentioned "datum plane which passes through a shoulder of a valve stem block." *See supra* Sections III.B, VI.B.1.a.

620. As with the limitation that contains the term "canister fire configuration," Mr. Anderson's analysis of the limitations "canister fire sequence," "first reset position," and "count configuration" under Defendants' proposed constructions relies on an analysis of Figures 7 and 12 of the '021 Publication, which he extrapolates to other figures—here, Figures 48 and 40.



See Anderson Opening Rep. ¶¶ 337-339.

621. In my opinion, Mr. Anderson's analysis of these limitations is flawed for the same reasons as his analysis of the limitation that contains the term "canister fire configuration." In brief, Mr. Anderson's identification of the "datum plane" in Figures 48 and 40 based on the location of orifice 20 in Figures 7 and 12 is unsupported, as I explained above. *Supra* Section VI.B.1.a.1)b). Even assuming, contrary to my opinion, that Mr. Anderson's identification of the datum plane in Figures 7 and 12 were correct, there is no basis for his extrapolation of the location

of the “datum plane” in the other figures, including Figures 48 and 40. Simply put, nothing in Figures 12 or 7 depicts the dose indicating mechanism; thus, they do not depict where in the dose indicating mechanism the datum plane as drawn by Mr. Anderson would fall. And nothing in Figures 40 or 48 depicts a valve stem block, much less a shoulder of a valve stem block, such that a datum plane could be placed. I cannot determine how Mr. Anderson made this flawed extrapolation, but see no basis to support it. Indeed, a comparison of Mr. Anderson’s marked-up figures illustrates that even Mr. Anderson’s efforts to place the datum plane do not appear to be internally consistent because, across those embodiments, he places the datum plane at different heights relative to the valve stem.

622. In addition, and as I explained above, the ’021 Publication makes clear that its various descriptions and figures refer to different, “alternative embodiments” of the purported invention(s), *see, e.g.*, ’021 Publication, ¶¶ [0024]-[0035], [0047], [0062]-[0064], [0071], and that within these embodiments, the invention(s) can be configured to comprise a variety of components, each of which can be configured in a variety of shapes and sizes, *see, e.g.*, ’021 Publication, ¶¶ [0076], [0096]. Thus, the POSA would not understand that the location of a particular component in one embodiment (e.g., as shown in Figures 12 and 7) could be extrapolated to determine the existence or location of a corresponding component in different embodiments (e.g., as shown in Figures 40 and 48). Thus, as relevant here, the POSA would not understand embodiments described and/or depicted in figures other than Figures 12 and 7 would comprise an orifice 20 or similar orifice in the same or similar location.

623. Third, as with the figures discussed above, the ’021 Publication does not support Mr. Anderson’s assertion that Figures 40 or 48 depicts the device in any particular configuration relative to the moment at which medication fires. *See supra* Section VI.B.1.a.1)a). Thus, Mr.

Anderson's analysis fails in any event.

2) Claim 9

624. Asserted Claim 9 depends from Asserted Claim 1 and recites: "A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." In my opinion, at a minimum, the '021 Publication does not disclose a "dose counter as claimed in claim 1." *See supra* Section VI.B.1.a.1). Thus, the '021 Publication does not anticipate this claim.

3) Claim 11

625. Asserted Claim 11 depends from Asserted Claim 1 and recites: "An inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1." In my opinion, at a minimum, the '021 Publication does not disclose a "dose counter as claimed in claim 1." *See supra* Section VI.B.1.a.1). Thus, the '021 Publication does not anticipate this claim.

4) Claim 12

626. Asserted Claim 12 depends from Asserted Claim 11 and recites: "An inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator." In my opinion, at a minimum, the '021 Publication does not disclose an "inhaler as claimed in claim 11." *See supra* Section VI.B.1.a.3). Thus, the '021 Publication does not anticipate this claim. I address Mr. Anderson's opinion that the term "the body" is indefinite below. *See infra* Section VI.B.3.

5) Claim 13

627. Asserted Claim 13 depends from Asserted Claim 1 and recites: “The dose counter of claim 1, wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister.” As I explain above, in my opinion, the ’021 Publication does not disclose, at a minimum, the “dose counter of claim 1.” *See supra* Section VI.B.1.a.1). Additionally, the remaining language in Asserted Claim 13 mirrors Defendants’ proposed construction of the term “datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.” For the reasons explained above in connection with Asserted Claim 1, the ’021 Publication does not disclose that limitation under Defendants’ proposed construction. *See supra* Section VI.B.1.a.1). Thus, the ’021 Publication does not anticipate this claim.

b. The ’552 Publication Does Not Anticipate the Asserted Claims of the ’156 Patent

628. In his Supplemental Report, Mr. Anderson opines that the ’552 Publication anticipates the Asserted Claims of the ’156 Patent. *See* Anderson Supp. Rep. § XII. I disagree. In my opinion, the POSA would not understand the ’021 Publication to disclose the limitations of the Asserted Claims as arranged in those claims. I incorporate by reference my analysis of the ’552 Publication in Section IV.B as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) Mr. Anderson’s “Summary of the Relevant Prosecution History”

629. Mr. Anderson’s Supplemental Report sets forth a lengthy summary of portions of the ’156 Patent’s prosecution history. *See* Anderson Supp. Rep. § XII.A. Notwithstanding that, Mr. Anderson does not appear to actually rely on any portion of the prosecution history in offering his opinions on invalidity. *Compare* Anderson Supp. Rep. § XII.A *with* Anderson Supp. Rep.

§ XII.B.³ I have reviewed the portions of the prosecution history that Mr. Anderson mentions. *See* Original Application (Apr. 29, 2015); Office Action (June 17, 2016); Office Action Response (Sep. 9, 2016); Office Action (Oct. 20, 2016); Office Action Response (Feb. 21, 2017); Office Action (Mar. 13, 2017); Office Action Response (Apr. 20, 2017); Office Action (May 5, 2017); Office Action Response (Aug. 22, 2017); Office Action (Sept. 13, 2017); Office Action Response (Mar. 13, 2018); Notice of Allowance (May 31, 2018); U.S. Patent No. 6,446,627 (“Bowman”).

630. In my opinion, the prosecution history of the ’156 Patent does not support Mr. Anderson’s opinion that the ’552 Publication anticipates the Asserted Claims, and in fact, contradicts it. For example, as I explain below in further detail, the prosecution history contradicts Mr. Anderson’s opinion that the ’552 Publication discloses an “actuator pawl” that “is below a datum plane which passing through a shoulder of the valve stem block.” *See infra* Section VI.B.1.b.3)b).

2) The ’552 Publication Does Not Disclose the Limitations of the Asserted Claims as Arranged in Those Claims.

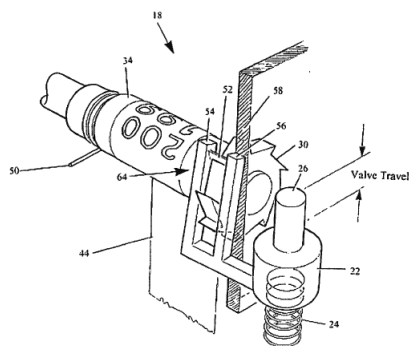
631. As an initial matter, in my opinion, the ’552 Publication does not anticipate any Asserted Claim of the ’156 Patent because the ’552 Publication does not disclose the limitations of the Asserted Claims as arranged in the claim. Notably, Mr. Anderson does not opine that any single disclosure within the ’552 Publication discloses every limitation of any Asserted Claim. Instead, as to each of the Asserted Claims, Mr. Anderson relies on a select number of disparate descriptions and figures in the 552 Publication. *See, e.g.*, Anderson Supp. Rep. § XII.B (citing

³ Mr. Anderson states that he disagrees with the infringement opinions that I offered in my Opening Reports, “including at least that a POSA would understand from the Prosecution History of the ’156 Patent that the datum plane could not encompass the plane drawn as Dr. Lewis proposes and still allow the patentees to rely on it to overcome the Examiner’s rejection over Bowman as occurred during prosecution.” Anderson Opening Rep. ¶ 50. If asked, I will consider Mr. Anderson’s forthcoming non-infringement opinions when he submits them.

'552 Publication, Abstract, 1:15-18, 1:20-21, 3:26-30, 4:5-6, 4:12-13, 8:7-9, 8:10-17, 8:15-17, 9:21-31, 10:10, 10:10-12, 19:26-11:4, 12:11-19, Figs. 2, 5, 8).

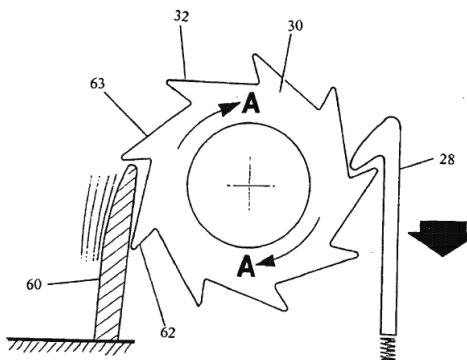
632. In my opinion, the POSA would not have focused on those or treated them as a single disclosure or embodiment. To justify his reliance on those disparate descriptions and figures, Mr. Anderson relies on what he characterizes as the '552 Publication's explanation "that 'the dose counter of the present invention' [']is based on that set out in [WO '033] except that the pawl 60 has been modified.'" Anderson Supp. Rep. ¶ 35 (citing '552 Publication, 8:7-9). Mr. Anderson infers, based on his interpretation of the '552 Publication, this "to mean that the locations of the actuator pawl and the valve stem block shown in both Bowman [i.e., the U.S. patent corresponding to WO '033] and the '552 Publication to be the same." Anderson Supp. Rep. ¶ 35 (citing Bowman, Fig. 2; '552 Publication, Fig. 2). I disagree with Mr. Anderson's interpretation.

633. As cited by Mr. Anderson, the '552 Publication states: "The *dose counter* of the present invention is based on that set out in Figs 3 and 4 described hereinabove except that the pawl 60 has been modified. Modification of the pawl followed an in-depth study of all of the components of the inhaler." '552 Publication, 8:7-9. Figures 3 and 4 of the '552 Publication and WO '033 depict identical mechanisms and describe the *dose counter* disclosed in WO '033.



(Prior art)

Fig. 3



(Prior art)

Fig. 4

'522 Publication, Figs. 3-4.

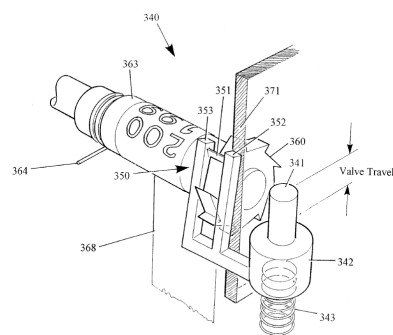


Figure 3

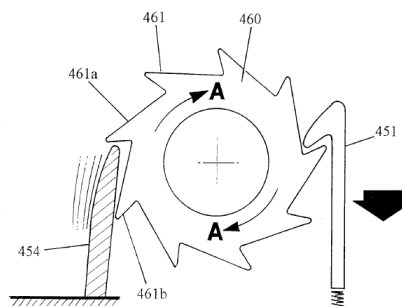


Figure 4

WO '033, Figs. 3-4.

634. Contrary to Mr. Anderson's interpretation, the POSA would not infer from the '552 Publication that the "locations of the actuator pawl and the valve stem block" were the same for the '552 Publication and WO '033 and/or Bowman. The POSA would understand that, with the exception of pawl 60, the '552 Publication's *dose counter* was based on that set forth in WO '033. But the POSA would not infer from that the relative locations of the actuator pawl and valve stem block were the same. Instead, the POSA would understand that the modification of pawl 60 "followed an in-depth study of all of the components of the inhaler." '552 Publication, 8:7-9.

Based on this statement and his or her knowledge of inhaler design, the POSA would understand that the designs of pawl 60 and the other inhaler components were related; and that a change in the design of pawl could affect the design of the valve stem block

635. Indeed, given the proximity between pawl 60 and the valve stem block, the POSA would not be able to infer, without additional information that the '552 Publication does not provide, that the “locations of the actuator pawl and the valve stem block” were the same for the '552 Publication and WO '033 and/or Bowman. Thus, as I explain below in further detail, at a minimum, the POSA would not infer that the '552 Publication discloses a dose counter wherein “in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister” based on the embodiments disclosed in the '552 Publication and WO '033 and/or Bowman. *See infra* Section VI.B.1.b.3)b). Nor would the POSA be able to infer the position of the actuator pawl relative to that “datum plane” in other stages of operation, as required by Defendants’ proposed construction of certain claim terms. *See infra* Section VI.B.1.b.3)c).

636. Mr. Anderson’s selective reliance on elements across embodiments in the '552 Publication and WO '033 provides further evidence that his analysis is based on a hindsight-driven effort to reconstruct the inventions recited in the Asserted Claims rather than a genuine effort to understand how the POSA would have understood the prior art.

3) Claim 1

a) The '552 Publication Does Not Disclose Firing Before Counting

637. Additionally, in my opinion, the '552 Publication does not anticipate Asserted Claim 1 of the '156 Patent (and, therefore, does not anticipate any Asserted Claim) because it does not disclose the limitation “wherein the actuator is further arranged such that, during a canister fire

sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.” As explained above, under both sides’ constructions, that limitation requires the “canister fire configuration” to occur before the “count configuration.”

638. Mr. Anderson opines that the ’552 Publication discloses this limitation (which he addresses in connection with what he terms Limitation 1F) because it discloses a dose counter in which the “count configuration” occurs “just after the canister fires (e.g., is in the canister fire configuration).” Anderson Supp. Rep. ¶ 44; Anderson Opening Rep. ¶ 368 (citing ’552 Publication, 10:26-11:4). For support, Mr. Anderson relies on the following statement: “Where the metered-dose inhaler is a pressurized inhaler, the stroke available for counting is equal to the full stroke of the medicament canister 6.” See Anderson Supp. Rep. ¶ 44; Anderson Opening Rep. ¶ 368; ’552 Publication, 10:26-11:4. However, that statement does not support his opinion.

639. Instead, the statement in the ’552 Publication that Mr. Anderson relies upon states that the “stroke *available* for counting” (i.e., the change in canister position that can, but need not be used to cause the dose counting mechanism to count) is “equal to the full stroke of the medicament canister” (i.e., the change in canister position that can, but need not be used to cause the device to fire). Contrary to Mr. Anderson’s opinion, that does not imply that the device fires before counting; nor does it imply any relationship between the two. Depending on the designs of the dose indicating mechanism (including, for example, the length of the actuator), valve (including, for example, the designs of the ferrule and gasket), valve stem, and valve stem block,

the “canister fire configuration” could occur simultaneously with or after the “count configuration.” Indeed, even assuming, as Mr. Anderson appears to do, that the device counts and fires at the end of the associated stroke, the description Mr. Anderson relies upon would imply that the two occur simultaneously.

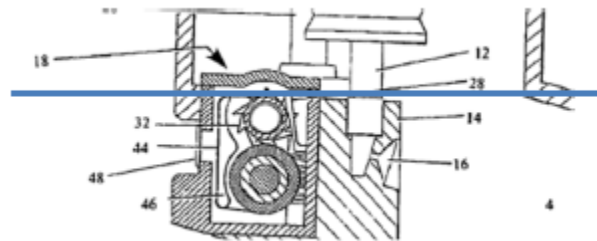
640. The POSA would have good reason not to interpret the ’552 Publication to disclose a dose counter in which the “canister fire configuration” occurs before the “count configuration. As I describe below in greater detail in addressing Mr. Anderson’s opinions on obviousness, the prior art as a whole taught away from devices in which the “canister fire configuration” occurs before the “count configuration” because it taught that undercounting (the risk associated with devices that fire before counting) would be dangerous because it could lead a patient to use a device that beyond its number of recommended doses and, as a result, receive an incorrect and potentially insufficient drug dose. *See, e.g.*, FDA Guidance 2003, TEVAQVAR-00032577-78; *infra* Section VI.B.2.a.2)a). Consistent with those teachings, the ’552 Publication itself states: “Clearly, undercounting is particularly undesirable as it can lead to a patient believing that there are more doses left within the inhaler than there actually are.” ’552 Publication, 7:16-24. In view of the prior art’s teachings about the dangers of undercounting, and the ’552 Publication’s express recognition of those dangers, the POSA would not have understood the ’552 Publication to disclose a device designed to increase the likelihood of undercounting (i.e., one in which the “canister fire configuration” occurs before the “count configuration”). Instead, the POSA would have understood it to disclose the opposite (i.e., one in which the “count configuration” occurs before the “canister fire configuration.”).

b) The ’552 Publication Does Not Disclose an “Actuator Pawl” Below the “Datum Plane” in the “Canister Fire Configuration”

641. Additionally, in my opinion, the ’552 Publication does not anticipate Asserted

Claim 1 of the '156 Patent (and, therefore, does not anticipate any Asserted Claim) because it does not disclose the limitation “wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.”

642. Mr. Anderson opines that the '552 Publication discloses this limitation (in connection with what he terms Limitations 1F and 1G) based on a flawed analysis of Figure 2 of the '552 Publication. I reproduce Mr. Anderson's marked-up version of Figure 2 below.



See Anderson Supp. Rep. ¶ 52.

643. Assuming, for argument's sake, that Mr. Anderson's “datum plane” passes “through a shoulder of the valve stem block,” I disagree that Figure 2 discloses an “actuator pawl” that is below this “datum plane” in the “canister fire configuration.”

644. According to Mr. Anderson, Figure 2 depicts a dose counter comprising an “actuator pawl” (which he identifies as “driver 28”), which engages with a first tooth of a ratchet wheel. Anderson Supp. Rep. ¶ 53; Anderson Opening Rep. ¶ 378. Mr. Anderson asserts that Figure 2 depicts the dose counter in the “start” or “rest” position or configuration “due to the extension of the canister and the actuator pin.” Anderson Supp. Rep. ¶ 53; Anderson Opening Rep. ¶ 370. Mr. Anderson asserts that during the device's operation, the “actuator pawl” moves further downward. *See* Anderson Supp. Rep. ¶ 53; Anderson Opening Rep. ¶ 370. Notwithstanding that, Mr. Anderson asserts that it does not matter whether Figure 2 depicts a dose

counter in the “start configuration,” “canister fire configuration,” or “first reset position” because Figure 2 itself depicts that an “actuator pawl” that is beneath the relevant “datum plane.” *See* Anderson Supp. Rep. ¶ 53. Mr. Anderson’s analysis is flawed for multiple reasons.

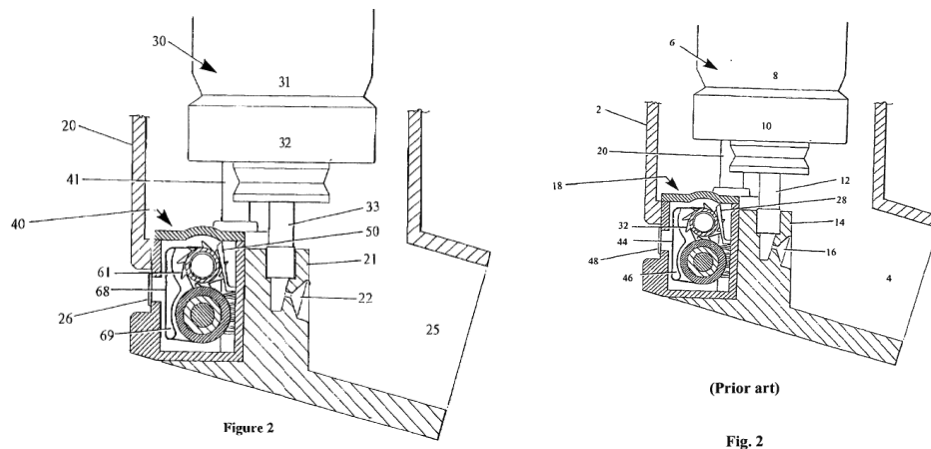
645. As an initial matter, Mr. Anderson’s analysis of the relative locations of the “actuator pawl” and “a datum plane which passes through a shoulder of the valve stem block” depends on his assumption that although Figure 2 depicts a prior-art device disclosed in WO ’033, “the ’552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed.” Anderson Supp. Rep. ¶ 46; Anderson Opening Rep. ¶ 370 (citing ’552 Publication, 8:7-8). As I explain above, that assumption is incorrect. To the contrary, the POSA would have understood from the ’552 Publication’s disclosure that the ’552 Publication’s dose counter comprised a “modified” pawl 60, which “followed an in-depth study of all of the components of the inhaler, ’552 Publication, 8:7-9, that no such inferences could be drawn. As a result, the POSA would not have treated the ’552 Publication’s reproduction of the WO ’033 device (depicted in, for example, Figure 2) and the ’552 Publication’s other disclosures that Mr. Anderson relies upon for other limitations, *see, e.g.*, Anderson Supp. Rep. ¶¶ 7-40; Anderson Opening Rep. ¶¶ 359-362, as a single disclosure or embodiment. Nor would the POSA be able to infer the relative locations of the “actuator pawl” and “datum plane.”

646. Additionally, even assuming, contrary to my opinion, that the POSA would have treated Figure 2 and the other disclosures as a single disclosure or embodiment, Mr. Anderson’s assertion that Figure 2 depicts the device in the “rest” or “start” position or configuration is without basis. The ’552 Publication provides no support for that assertion. *See, e.g.*, ’552 Publication, 3:15-5:10, Fig. 2. Instead, Mr. Anderson derives it from his belief that Figure 2 depicts the medicament canister and actuation pin in an extended position. *See* Anderson Supp. Rep. ¶ 53;

Anderson Opening Rep. ¶ 370. However, in my opinion, no such inference can be drawn. To infer whether Figure 2 depicts the medicament canister and actuation pin in an extended position, the POSA would need to know how far downwards the medicament canister and actuation pin traveled during operation—and the '552 Publication provides no such information.

647. In my opinion, Mr. Anderson is also mistaken that Figure 2 depicts an “actuator pawl” that is below a “datum plane which passes through a shoulder of a valve stem block.” Even assuming, for argument’s sake, that Mr. Anderson’s “datum plane” passes “through a shoulder of a valve stem block,” as Mr. Anderson’s own marked-up version of Figure 2 depicts, the “actuator pawl” actually extends above the “datum plane” he draws in that figure.

648. The '156 Patent’s prosecution history, which Mr. Anderson recounts, but ignores, confirms that Figure 2 of the '552 Publication does not disclose an “actuator pawl” that “is below a datum plane which passes through a shoulder of a valve stem block” in the “canister fire configuration.” In allowing the claims, the Examiner compared the claims Figure 9 of the '156 Patent to Figure 2 of Bowman, *see, e.g.*, '156 Patent File History, Office Action (Sept. 13, 2017); Office Action Response (Mar. 13, 2018); Notice of Allowance (May 31, 2018), which is materially identical to Figure 2 of the '552 Publication and WO '033.



'552 Publication, Fig. 2; Bowman, Fig. 2. That the Examiner conducted this comparison, but nevertheless allowed the claims provides further evidence that Mr. Anderson is incorrect.

c) The '552 Publication Does Not Disclose a “Canister Fire Sequence,” a “First Reset Position” or a “Count Configuration” Under Defendants’ Proposed Constructions

649. Additionally, in my opinion, the '552 Publication does not anticipate Asserted Claim 1 of the '156 Patent (and, therefore, does not anticipate any Asserted Claim of the '156 Patent) under Defendants’ proposed constructions of the terms “canister fire sequence,” “first reset position,” and “count configuration.” As shown in the table above, Defendants’ proposed constructions for those terms require the “actuator pawl” to have a specific location relative to the above-mentioned “datum plane which passes through a shoulder of a valve stem block.” *See supra* Sections III.B, VI.B.1.a.

650. As with the limitation that contains the term “canister fire configuration,” Mr. Anderson’s analysis of the limitations “canister fire sequence,” “first reset position,” and “count configuration” under Defendants’ proposed constructions relies on an analysis of Figure 2 of the '552 Publication and other, disparate disclosures. *See* Anderson Supp. Rep. ¶¶ 42-49. As I explain above, the POSA would not have viewed those disclosures as relating to a single disclosure or embodiment. Nor would the POSA have been able to draw any inferences about the relative location of the “actuator pawl” and a “datum plane which passes through a shoulder of the valve stem block.” *See supra* Section VI.B.1.b.2). I therefore disagree with Mr. Anderson’s analysis of these limitations.

4) Claim 2

651. Although Mr. Anderson does not purport to offer an opinion regarding obviousness of the Asserted Claims or to address the validity of claim 2 of the '156 Patent in his Supplemental

Report, *see, e.g.*, Anderson Supp. Rep. ¶¶ 3, 34, Paragraph 55 of his Supplemental Report states that claim 2 of the '156 Patent would have been obvious based on the '552 Publication and/or the POSA's knowledge. Paragraph 55 of Mr. Anderson's Supplemental Report appears to be word-for-word identical to Paragraph 377 of his Opening Report, which I address below. *See infra* Section VI.B.2.a.3). To the extent an additional response to Paragraph 55 of Mr. Anderson's Supplemental Report is required, my response is the same. *See infra* Section VI.B.2.a.3).

5) Claims 9 and 11-13

652. Asserted Claims 9 and 11-13 depend from Asserted Claim 1 and require, among other things, the "dose counter as claimed in claim 1" or the "dose counter of claim 1." In my opinion, at a minimum, the '552 Publication and/or the POSA's knowledge do not disclose the "dose counter as claimed in claim 1" or the "dose counter of claim 1." *See supra* Section VI.B.1.b.3). Thus, the '552 Publication fails to anticipate these claims for at least these reasons.

653. Additionally, Asserted Claim 13 recites the limitation "wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister." As I explain above, this language mirrors Defendants' proposed construction of the term "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." For the reasons explained above in connection with Asserted Claim 1, the '552 Publication does not disclose that limitation under Defendants' proposed construction. *See supra* Section VI.B.1.b.3). Thus, the '552 Publication does not anticipate Asserted Claim 13 for at least this additional reason.

* * *

654. I note that the '021 and '552 Publications were before the examiner during prosecution of the '156 Patent. *See, e.g.*, '156 Patent, Foreign Patent Documents. I have conducted an independent analysis of the '021 and '552 Publications, and in my opinion, the '021 and '552

Publications do not anticipate the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims provides further evidence that the '021 and '552 Publications do not anticipate those claims.

2. Mr. Anderson's Obviousness Theories are Incorrect

a. The '552 Publication Does Not Render Obvious the Asserted Claims of the '156 Patent

655. In his Opening Report, Mr. Anderson offers an alternative obviousness theory based on a different purported "datum plane which passes through a shoulder of a valve stem block." Specifically, Mr. Anderson opines that the '552 Publication and the POSA's knowledge render obvious claims 1-2, 9, and 11-13 of the '156 Patent. *See* Anderson Opening Rep. § XVI.B. I disagree. In my opinion, the '552 Publication does not disclose the inventions recited in those claims; and the POSA would not have had a reason to select, modify, and/or combine aspects of the '552 Publication and/or the POSA's knowledge to develop those inventions with a reasonable expectation of success. I incorporate by reference my analysis of the '552 Publication in Section IV.B as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) The POSA Would Not Have Had a Reason to Select the '552 Publication for Modification

656. As an initial matter, in my opinion, the '552 Publication and/or the POSA's knowledge does not render obvious any claim of the '156 Patent because the POSA would not have had a reason to select the '552 Publication as the basis for designing an inhaler and/or dose counter. Mr. Anderson offers no such reason in his report. As I explain in my opinions regarding objective indicia of non-obviousness and above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting

mechanisms should be selected, modified, and/or combined. *See* Lewis Opening Rep. §§ IX.A-B; *supra* Sections VI.A.2 and Section V.

657. Additionally, as I explain above in responding to Mr. Anderson’s anticipation opinions relating to the ’552 Publication, the POSA would not had a reason to select the disparate descriptions and figures that Mr. Anderson relies upon, *see, e.g.*, Anderson Supp. Rep. § XII.B (citing ’552 Publication, Abstract, 1:15-18, 1:20-21, 3:26-30, 4:5-6, 4:12-13, 8:7-9, 8:10-17, 8:15-17, 9:21-31, 10:10, 10:10-12, 19:26-11:4, 12:11-19, Figs. 2, 5, 8), and would not have viewed them as a single disclosure or embodiment. To the contrary, the POSA would have understood from the ’552 Publication’s disclosure that the ’552 Publication’s dose counter comprised a “modified” pawl 60, which “followed an in-depth study of all of the components of the inhaler, ’552 Publication, 8:7-9, that no such inferences could be drawn. As a result, the POSA would not have treated the ’552 Publication’s reproduction of the WO ’033 device (depicted in, for example, Figure 2) and the ’552 Publication’s other disclosures that Mr. Anderson relies upon for other limitations, *see, e.g.*, Anderson Supp. Rep. ¶¶ 7-40; Anderson Opening Rep. ¶¶ 359-362, as a single disclosure or embodiment.

658. Thus, as I explain below in further detail, at a minimum, the POSA would not infer that the ’552 Publication renders obvious a dose counter wherein “in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister” based on the embodiments disclosed in the ’552 Publication and WO ’033 and/or Bowman. *See infra* Section VI.B.2.a.2)b). Nor would the POSA be able to infer the position of the actuator pawl relative to that “datum plane” in other stages of operation, as required by Defendants’ proposed construction of certain claim terms. *See infra* Section VI.B.2.a.2)c).

659. Once again, Mr. Anderson's selective reliance on the '552 Publication provides further evidence that his analysis is based on a hindsight-driven effort to reconstruct the inventions recited in the Asserted Claims rather than a genuine effort to understand how the POSA would have understood the prior art.

2) Claim 1

a) The '552 Publication Does Not Render Obvious Firing Before Counting

660. Additionally, in my opinion, the '552 Publication and/or the POSA's knowledge does not render obvious Asserted Claim 1 of the '156 Patent (and, therefore, does not render obvious any Asserted Claim) because it does not render obvious the limitation "wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count." As explained above, under both sides' constructions, that limitation requires the "canister fire configuration" to occur before the "count configuration."

661. In my opinion, the POSA would not have had a reason to develop a device in which the "canister fire configuration" occurred before the "count configuration" with a reasonable expectation of success. To the contrary, the POSA would have desired to develop a device in which the "count configuration" occurred before the "canister fire configuration" and would have expected that a device in which the "count configuration" occurred before the "canister fire configuration" would be unsuitable, including, for example, because it would bias the device toward undercounting errors rather than overcounting errors.

662. Considered as a whole, the prior art taught away from devices in which the “canister fire configuration” occurs before the “count configuration.” The prior art taught that undercounting (the risk associated with devices that fire before counting) would be dangerous because it could lead a patient to use a device that beyond its number of recommended doses and, as a result, receive an incorrect and potentially insufficient drug dose. *See, e.g.*, FDA Guidance 2003, TEVAQVAR-00032577-78. Although the prior art also taught that overcounting should be minimized because it was potentially wasteful, FDA Guidance 2003, TEVAQVAR-00032577, the POSA would have understood that the comparative risks of undercounting were much more significant than the risks of overcounting and that, as a result, devices should be designed to be biased towards overcounting. This is precisely how FDA’s 2003 Guidance instructed the industry to develop their devices: “[I]f some low frequency of error is unavoidable, the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance). Undercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.” FDA Guidance 2003, TEVAQVAR-00032578. Indeed, consistent with FDA’s guidance, the ’552 Publication itself states: “Clearly, undercounting is particularly undesirable as it can lead to a patient believing that there are more doses left within the inhaler than there actually are.” ’552 Publication, 7:16-24.

663. My own experience confirms this. As of the priority date, I was responsible for designing inhalation aerosol devices at Vectura and Chiesi. At the time, based on the understanding of these comparative risks of undercounting and overcounting, the conventional wisdom was to develop devices that counted before firing.

664. Mr. Anderson opines that the ’552 Publication renders obvious a device in which the “canister fire configuration” occurs before the “count configuration” (which he addresses in

connection with what he terms Limitation 1F) because it discloses a dose counter in which the “count configuration” occurs “just after the canister fires (e.g., is in the canister fire configuration).” Anderson Opening Rep. ¶ 368 (citing ’552 Publication, 10:26-11:4). For support, Mr. Anderson relies on the following statement: “Where the metered-dose inhaler is a pressurized inhaler, the stroke available for counting is equal to the full stroke of the medicament canister 6.” ’552 Publication, 10:26-11:4. However, that statement does not support his opinion.

665. Instead, the statement in the ’552 Publication that Mr. Anderson relies upon states that the “stroke *available* for counting” (i.e., the change in canister position that can, but need not be used to cause the dose counting mechanism to count) is “equal to the full stroke of the medicament canister” (i.e., the change in canister position that can, but need not be used to cause the device to fire). Contrary to Mr. Anderson’s opinion, that does not imply that the device fires before counting; nor does it imply any relationship between the two. Depending on the design of the dose indicating mechanism, valve stem, and valve stem block, the “canister fire configuration” could occur simultaneously with or after the “count configuration.” Indeed, even assuming, as Mr. Anderson appears to do, that the device counts and fires at the end of the associated stroke, the description Mr. Anderson relies upon would imply that the two occur simultaneously.

666. Teva’s research and development of the claimed inventions further reflects the non-obviousness of a dose counter in which the “canister fire configuration” occurs before the “count configuration.” In the course of researching and developing the claimed inventions, the inventors undertook a rigorous, multi-phase design process, which involved a combination of mathematical modeling and physical testing, to ensure that the resulting device and its components satisfied the tolerances needed to minimize overcounting. *See, e.g.*, TEVAQVAR-00764323 (ProAir® HFA Design History File); TEVAQVAR-00763343; TEVAQVAR-00763398; TEVAQVAR-

00763430; TEVAQVAR-00763452; TEVAQVAR-00763520; TEVAQVAR-00763540; TEVAQVAR-00763552 (ProAir® HFA Phase Review Presentations); TEVAQVAR-00763677 (ProAir® HFA Phase II Final Analysis Report); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); '156 Patent, 11:42-44, 17:24-61, Fig. 9, 11, 14.

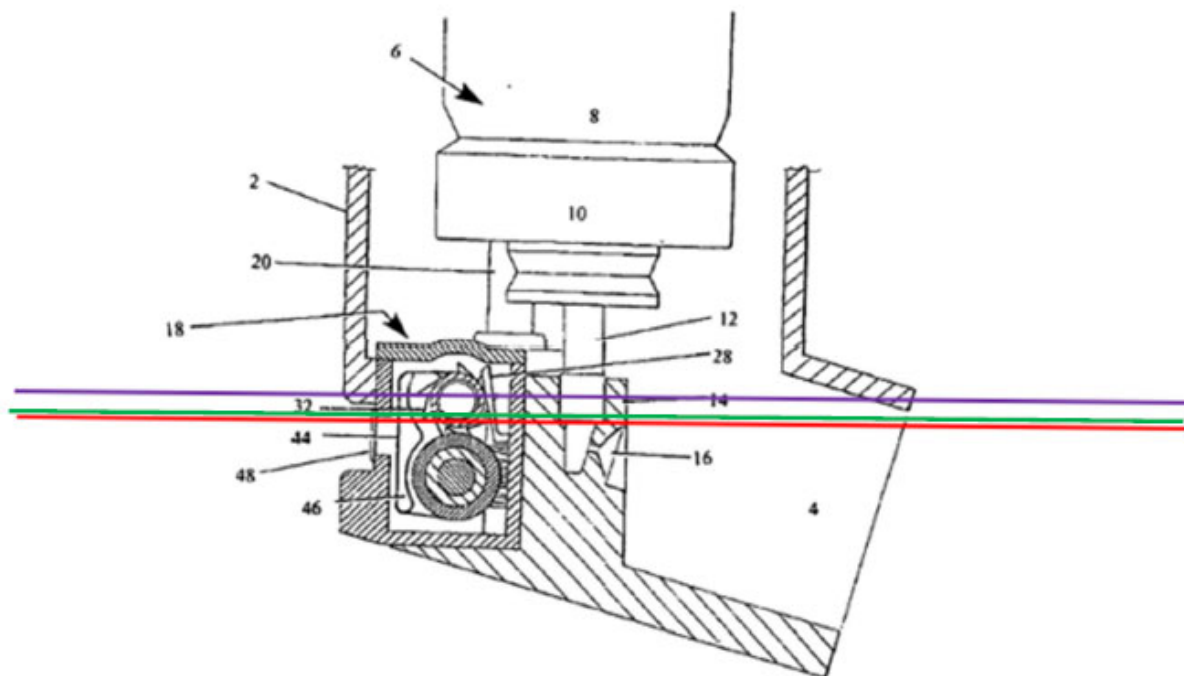
667. As part of this analysis, the inventors implemented a complex, computer-assisted tolerance analysis to estimate the feasibility space (i.e., the set of potentially “feasible” or workable candidate solutions) for the device’s components, including their sizes and shapes, positions, and movements. *See, e.g.*, TEVAQVAR-00763552 (ProAir® HFA Phase Review Presentation); TEVAQVAR-00763677 (ProAir® HFA Phase II Final Analysis Report); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); '156 Patent, 11:42-44, 17:24-61, Fig. 9, 11, 14. Based on this analysis, the inventors unexpectedly discovered that, contrary to Teva’s initial expectations, it would be preferable to design the device such that it counted *before* firing rather than *after* firing. *See, e.g.*, TEVAQVAR-00763552, at -554 (ProAir® HFA Phase Review Presentation) (“Teva asked Radius to investigate making minor design changes to the BAI counter such that it could be installed in the C2 inhaler and reliably count before the canister reached its firing point. Achieving that goal is not possible.”), -555-73; '156 Patent, 11:42-44, 17:24-61, Fig. 9, 11, 14. That the inventors arrived at this conclusion only after extensive trial and error provides further evidence that this limitation would not have been obvious.

b) The '552 Publication Does Not Render Obvious an “Actuator Pawl” Below the “Datum Plane” in the “Canister Fire Configuration”

668. Additionally, in my opinion, the '552 Publication and/or the POSA’s knowledge does not render obvious Asserted Claim 1 of the '156 Patent (and, therefore, does not render obvious any Asserted Claim) because it does not render obvious the limitation “wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a

shoulder of a valve stem block configured to receive the medicament canister.”

669. To support his contrary opinion, Mr. Anderson offers a flawed analysis of what appears to be a marked-up version of Figure 2 of the '552 Publication (again, in connection with what he terms Limitations 1F and 1G). I reproduce Mr. Anderson's marked-up figure below.



Anderson Opening Rep. ¶ 370.

670. As discussed above in connection with Mr. Anderson's anticipation opinions, according to Mr. Anderson, Figure 2 depicts a dose counter comprising an “actuator pawl” (which he identifies as “driver 28”), which engages with a first tooth of a ratchet wheel. Anderson Supp. Rep. ¶ 53; Anderson Opening Rep. ¶ 378. Mr. Anderson asserts that Figure 2 depicts the dose counter in the “start” or “rest” position or configuration “due to the extension of the canister and the actuator pin.” Anderson Supp. Rep. ¶ 53; Anderson Opening Rep. ¶ 370. Mr. Anderson asserts that when the device moves a “full stroke,” the ratchet wheel moves “one full tooth pitch, which would bring the first tooth from the purple line to the green line,” the latter of which he

identifies as “approximately at or slightly above” the “datum plane line,” which passes through a shoulder of a valve stem block. Anderson Opening Rep. ¶ 370. As before, Mr. Anderson’s analysis is flawed for multiple reasons.

671. As an initial matter, as I explain above, Mr. Anderson does not identify any reason why the POSA would have selected the ’552 Publication for modification. Nor does he identify any reason why the POSA would have selected Figure 2 from among the ’552 Publication’s disclosures. As I explain above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined, *see supra* Section V, and Mr. Anderson’s selective reliance on Figure 2 as the basis for modification provides further evidence that his analysis is based on hindsight.

672. Additionally, as I explain above, Mr. Anderson’s analysis of the relative locations of the “actuator pawl” and “a datum plane which passes through a shoulder of the valve stem block” depends on his assumption that although Figure 2 depicts a prior-art device disclosed in WO ’033, “the ’552 Publication makes clear that the invention is essentially the same as the prior art except that the count pawl 60 has been changed.” Anderson Supp. Rep. ¶ 46; Anderson Opening Rep. ¶ 370 (citing ’552 Publication, 8:7-8). As I explain above, that assumption is incorrect. To the contrary, the POSA would have understood from the ’552 Publication’s disclosure that the ’552 Publication’s dose counter comprised a “modified” pawl 60, which “followed an in-depth study of all of the components of the inhaler, ’552 Publication, 8:7-9, that no such inferences could be drawn. As a result, the POSA would not have treated the ’552 Publication’s reproduction of the WO ’033 device (depicted in, for example, Figure 2) and the

'552 Publication's other disclosures that Mr. Anderson relies upon for other limitations, *see, e.g.*, Anderson Supp. Rep. ¶¶ 7-40; Anderson Opening Rep. ¶¶ 359-362, as a single disclosure or embodiment. Nor would the POSA be able to infer the relative locations of the "actuator pawl" and "datum plane." *See supra* Section VI.B.2.a.1).

673. Additionally, as I explain above, even assuming, contrary to my opinion, that the POSA would have selected and combined the aspects of the '552 Publication that Mr. Anderson relies upon, Mr. Anderson's assertion that Figure 2 depicts the device in the "rest" or "start" position or configuration is without basis. The '552 Publication provides no support for that assertion. *See, e.g.*, '552 Publication, 3:15-5:10, Fig. 2. Instead, Mr. Anderson derives it from his belief that Figure 2 depicts the medicament canister and actuation pin in an extended position. *See* Anderson Supp. Rep. ¶ 53; Anderson Opening Rep. ¶ 370. However, in my opinion, no such inference can be drawn. To infer whether Figure 2 depicts the medicament canister and actuation pin in an extended position, the POSA would need to know how far downwards the medicament canister and actuation pin traveled during operation—and the '552 Publication provides no such information. *See supra* Section VI.B.1.b.3)b).

674. Mr. Anderson's assertion that when the device depicted in Figure 2 moves a "full stroke," the ratchet wheel moves "one full tooth pitch, which would bring the first tooth from the purple line to the green line," Anderson Opening Rep. ¶ 370, is likewise without basis. Again, the '552 Publication provides no support for that assertion. *See, e.g.*, '552 Publication, 3:15-5:10, Fig. 2. Based on Figure 2 and the accompanying descriptions, the POSA would be unable to determine what stage of operation the device was in; whether driver 28 was engaged with a first tooth of the ratchet wheel; whether, assuming driver 28 was engaged with a first tooth of a ratchet wheel where that engagement occurred; and where driver 28 would be located in other stages of operation—

each of which would be needed to make the precise determinations about the relative locations of the “actuator pawl” and the “datum plane passing through a shoulder of a valve stem block” required to evaluate obviousness.

675. Were each of these flaws not, by themselves, enough for the POSA to reject Mr. Anderson’s obviousness theory (and in my opinion, they would have been), the POSA *still* would have concluded that the ’552 Publication did not render obvious a device wherein the “actuator pawl” was “below a datum plane passing through a shoulder of a valve stem block” in the “canister fire configuration.”

676. Even according to Mr. Anderson, for purposes of his obviousness theory, Figure 2 does not depict that driver 28 ever moves below what he identifies as the “datum plane.” Notwithstanding that, he asserts:

The datum plane is generally located at the point where the valve stem sits in the stem block. It is from this reference plane/point that the valve will typically open at a known distance when the cannister is pushed down this minimum distance and the valve opens and allows fluid (propellant and medication) to exit. Bringing the dose counter mechanism closer to this point (and the datum plane) allows for more accurate counting as tolerances from this plane are more controlled as there are less variables. The canister in the ’552 Publication, as shown above, moves a single pin to trigger the dose counter. This single pin would be more prone to distortion or bending during use as it has a gap between the actuator and the shelf and this could be exacerbated with the user not pushing the cannister centrally. Arranging the dose counter so that counting occurs very near to valve firing, will create less need for movement and therefore less room for error. Thus, it would have been obvious for a person of skill to move the actuator down, thereby reducing the distance, if any, that must be covered between firing and counting and have it as short as possible to reduce the risk of distortion during actuation. As the ’552 Publication already teaches a dose counter, a person of skill in the art would have a reasonable expectation that the dose counter would still work, and be improved, if the dose counter mechanism was lowered or compressed slightly such that the actuator pawl crossed below the datum plane line in the fire

configuration. This change would reduce excessive play in the system.

Anderson Opening Rep. ¶ 371. I disagree with Mr. Anderson's opinions.

677. In my opinion, the POSA would not have had a reason to lower the dose counting mechanism in the manner that Mr. Anderson suggests with a reasonable expectation of success. To the contrary, the POSA would have desired to *avoid* lowering the dose counting mechanism in that manner and would have expected that such a modification would result in an unsuitable device. The POSA would have understood that lowering the dose counting mechanism would result in a number of undesirable mechanical consequences, including the need to redesign or revalidate the components of the dose counting mechanism, including with respect to their shapes, sizes, and tolerances; and/or evaluate any changes in air flow through the device caused by lowering the dose counting mechanism. The POSA would have understood that whether such a device would work properly would further depend on the dimensions and properties of the canister, valve, and valve stem selected for use in the device. The POSA would have understood that the canister might need to be positioned differently in the inhaler that or a different valve or valve stem might be required, to accommodate the newly lowered dose counting mechanism. Neither the '552 Publication nor the POSA's knowledge would have provided any meaningful guidance as to which of these changes should be made or which would prove successful.

678. In addition to these undesirable mechanical consequences, the POSA would understand that lowering the dose counting mechanism in the manner Mr. Anderson suggests would have undesirable human consequences. As the figure above depicts, lowering the dose counting mechanism in such a manner would require redesigning the shape of the canister housing to accommodate that change. The POSA would have understood that such a change would be undesirable because it would disrupt patients' expectations regarding the size and shape of the

device, which could affect their willingness to use it. That is especially true for dose counting mechanisms, such as the ones described in the '552 Publication, which are intended to be suitable for use in conjunction with commercial inhalers. *See, e.g.*, '552 Publication, 11:14-21.

679. By contrast, the purported problems that Mr. Anderson identifies would not have given the POSA a reason to modify the design depicted in Figure 2 of the '552 Publication by lowering its dose counting mechanism. For example, the POSA would not have assessed the devices disclosed in the '552 Publication and determined that they could be improved by minimizing the distance between the dose counting mechanism and the “point at which the valve stem sits in the stem block.” In particular, the POSA would not have believed that such an alteration would result in “more accurate counting” by reducing the number of “variables.” To the contrary, the POSA would understand that, in a device such as the one depicted in the figure, the (1) distance between the dose counting mechanism and the “point at which the valve stem sits in the stem block” and (2) the stroke length of the dose counting mechanism (i.e., the stroke-to-count) were independent variables. The POSA would understand that lowering the dose counting mechanism closer to the “point at which the valve stem sits in the stem block” would introduce additional, artificial constraints on the position and movement of that mechanism; but that doing so would not reduce the need to ensure that the dose counting mechanism could operate within those constraints. The POSA would understand that, far from reducing the number of variables to be optimized, such an action would introduce unnecessary complexity into the design and manufacturing processes, which reduce the number of feasible solutions. By way of analogy, if I am designing a house, imposing a rule that the living room must be the same size as the bedroom does not reduce the number of rooms. It just makes the design process harder because, in addition to all of the other design requirements, such as, for example, the need for the house must fit within

a particular lot, I must now ensure that the living room and the bedroom are the same size. The same is true of designing inhalers. Requiring the dose counting mechanism be at the same vertical position of the “point at which the valve stem sits in the valve stem block” does not reduce the number of variables. It just makes the design process harder it reduces the flexibility that I would otherwise have in selecting or modifying components to ensure that they satisfied other constraints, such as the need for the dose counting mechanism to encroach upon or interfere with the other components of the inhaler.

680. Likewise, the POSA would not have had a reason to lower the dose counting mechanism in order to reduce “the risk of distortion during actuation.” Mr. Anderson does not identify any basis for this assertion, and in my opinion and experience, such concerns would not have given the POSA a reason to lower the dose counting mechanism in the manner that Mr. Anderson suggests. To the contrary, the POSA would understand that, given the small magnitude of the distances that the ’552 Publication describes and the materials used for dose counter construction, *see, e.g.*, ’552 Publication, 8:19-24, 11:14-12:9, lowering the dose counting mechanism to a modest extent would not meaningfully affect the risk of distortion to the actuation pin. Moreover, even were the POSA to have such concerns, which in my opinion, he or she would not have had, the POSA would understand that the such a risk of distortion would be better addressed by, for example, using more resilient materials for the actuation pin. And were the POSA inclined to make changes in the design of the components, the POSA could reduce the size of the actuator pawl and/or actuator pin. Such changes would avoid the number of undesirable consequences that the POSA would have expected that lowering the dose counting mechanism would cause, including the need to redesign the canister housing and/or various dose counting mechanism components, or adverse effects on air flow and patient use.

681. I note that the '552 Publication does not itself suggest any problems with the designs that it discloses, much less the problems that Mr. Anderson purports to identify. Mr. Anderson's identification of these purported problems, notwithstanding the '552 Publication's disclosures, provides further evidence that his analysis is based on hindsight.

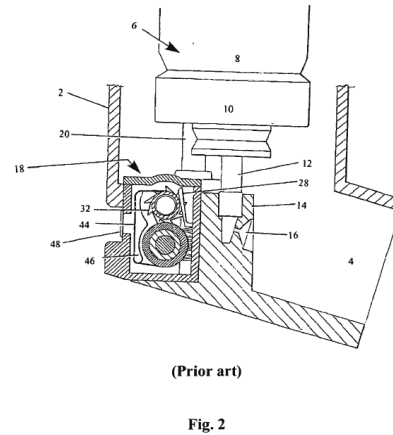
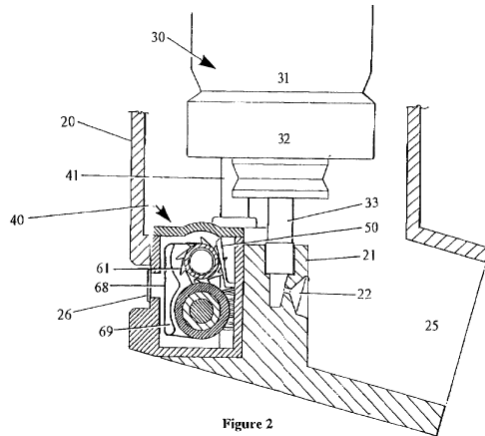
682. In any event, even were Mr. Anderson correct, which he is not, the purported problems that he identifies would not have given the POSA a reason to make the claimed inventions. At most, Mr. Anderson's arguments suggest that the POSA would have had a reason to lower the actuator pawl such that it was at the same vertical position as "the point where the valve stem sits in the stem block" at the end of its movement sequence. Thus, at most, the POSA would have lowered the actuator pawl such that it sat *on* a "datum plane which passes through a shoulder of a valve stem block" (which Mr. Anderson identifies as passing through the point where the valve stem sits in the stem block). However, the claims require the "actuator pawl" to be beneath a "datum plane which passes through a shoulder of a valve stem block." Thus, even on Mr. Anderson's account, the claimed inventions would not have been obvious.

683. Even assuming, contrary to my opinion, that the POSA would have had a reason to lower the dose counting mechanism, the POSA would not have expected to succeed in developing a suitable device. As explained above, the POSA would have expected that lowering the dose counting mechanism would have a number of undesirable consequences, including the need to redesign the canister housing and/or various dose counting mechanism components, and adverse effects on air flow and patient use. *See, e.g., supra* ¶ 275. Neither the '552 Publication nor the POSA's knowledge would have provided any meaningful guidance as to which of these changes should be made or which would prove successful. Instead, the POSA would have needed to test a large and unpredictable number of potential solutions, consisting of variations in the design and

position of the components of the inhaler or dose counting mechanism, without knowing which of those might succeed.

684. Teva's research and development of the claimed inventions further reflects the non-obviousness of a dose counter in which the "actuator pawl" was "below a datum plane which passes through a shoulder of a valve stem block" in the "canister fire configuration." As Teva's design documents demonstrate, Teva considered a number of different alternative designs, including by varying the lengths of the stroke-to-fire or stroke-to-count and the positions of the dose counter and actuator pawl. *See, e.g.*, TEVAQVAR-00764323 (ProAir® HFA Design History File); TEVAQVAR-00763343; TEVAQVAR-00763398; TEVAQVAR-00763430; TEVAQVAR-00763452; TEVAQVAR-00763520; TEVAQVAR-00763540; TEVAQVAR-00763552 (ProAir® HFA Phase Review Presentations); TEVAQVAR-00763677 (ProAir® HFA Phase II Final Analysis Report); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); '156 Patent, 11:42-44, 17:24-61, Fig. 9, 11, 14. That the inventors arrived at the final position of the actuator pawl and its movement sequence only after extensive trial and error provides further evidence that the limitation would not have been obvious.

685. As discussed above, the '156 Patent's prosecution history confirms that Figure 2 of the '552 Publication does not render obvious an "actuator pawl" that "is below a datum plane which passes through a shoulder of a valve stem block" in the "canister fire configuration." *See supra* Section VI.B.1.b.3)b). In allowing the claims, the Examiner compared the claims Figure 9 of the '156 Patent to Figure 2 of Bowman, *see, e.g.*, '156 Patent File History, Office Action (Sept. 13, 2017); Office Action Response (Mar. 13, 2018); Notice of Allowance (May 31, 2018); Bowman; *supra* Section VI.B.1.b.3)b), which is materially identical to Figure 2 of the '552 Publication and WO '033.



'552 Publication, Figure 2; Bowman, Figure 2. That the Examiner conducted this comparison, but nevertheless allowed the claims provides further evidence that Mr. Anderson is incorrect.

c) The '552 Publication Does Not Render Obvious a "Canister Fire Sequence," a "First Reset Position" or a "Count Configuration" Under Defendants' Proposed Constructions

686. Additionally, in my opinion, the '552 Publication does not render obvious Asserted Claim 1 of the '156 Patent (and, therefore, does not render obvious any Asserted Claim of the '156 Patent) under Defendants' proposed constructions of the terms "canister fire sequence," "first reset position," and "count configuration." As shown in the table above, Defendants' proposed constructions for those terms require the "actuator pawl" to have a specific location relative to the above-mentioned "datum plane which passes through a shoulder of a valve stem block." *See supra* Sections III.B, VI.B.1.

687. As with the limitation that contains the term "canister fire configuration," Mr. Anderson's analysis of the limitations "canister fire sequence," "first reset position," and "count configuration" under Defendants' proposed constructions relies on an analysis of Figure 2 of the '552 Publication and other, disparate disclosures. *See* Anderson Opening Rep. ¶¶ 364-373. As I explain above, the POSA would not have viewed those disclosures as relating to a single disclosure

or embodiment. Nor would the POSA have been able to draw any inferences about the relative location of the “actuator pawl” and a “datum plane which passes through a shoulder of the valve stem block.” *See supra* Section VI.B.2.a.2)b). I therefore disagree with Mr. Anderson’s analysis of these limitations.

3) Claim 2

688. Claim 2 of the ’156 Patent depends from Asserted Claim 1 and recites: “A dose counter as claimed in claim 1 in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.” In my opinion, at a minimum, the ’552 Publication and/or the POSA’s knowledge do not render obvious the “dose counter as claimed in claim 1.” *See supra* Section VI.B.2.a.2). Thus, the ’552 Publication and/or the POSA’s knowledge fail to render obvious this claim for at least this reason.

689. Additionally, in my opinion, the ’552 Publication and/or the POSA’s knowledge do not render obvious a dose counter “in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.”

690. To support the following opinion, Mr. Anderson asserts the following:

The ’552 Publication describes an existing inhaler with a canister stroke distance of 3.04 ± 0.255 mm. *See* ’552 Publication at 11:15-18. The publication further explained that the exemplary inhaler had a start gap of 0.85 ± 0.47 . With this gap, inhalers falling on the shorter end of the canister stroke (e.g., 2.785 mm), cannot fully rotate the ratchet wheel, leading to a failure in dose counting. *Id.* at 11:23-12:2. The ’552 Publication teaches that placing teeth of pawl 60, 0.6 mm apart, reduces the start gap, reducing the risk of miscounting. A person of skill in the art would have also been aware that, it is optimal to minimize travel distance between firing and counting, otherwise the inhaler might fire, but not count, resulting in incorrect dose counting. The force it requires for a user to fire their inhaler can be quite significant. For example, the ’552 Publication discloses that the force required to activate the device is about 15-30 N. If the actuator must be pressed downwards significantly after the user hears and feels the ejection of medication,

they are likely to release the device too early, causing undercounting.

Anderson Opening Rep. ¶ 376. Mr. Anderson continues:

Thus, a person of skill in the art would be motivated by the teachings in the '552 Publication, and patient experience, to maintain a shorter distance for the actuator device to move in order to register a dose count, and would it require no more than routine optimization to arrive at a distance of less than 1mm, particularly as the '552 Publication already taught improvements in accuracy where the travel distance between teeth of the count pawl is less than 1mm. Thus, claim 2 of the '156 Patent would have been obvious over the '552 Publication and the knowledge of the POSA.

Anderson Opening Rep. ¶ 377. I disagree with Mr. Anderson's analysis.

691. In my opinion, the POSA would not have had a reason to modify the '552 Publication such that the “the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations” with a reasonable expectation of success. To the contrary, the POSA would have desired to avoid making such a modification and would have expected that it would result in an unsuitable device.

692. Although Mr. Anderson states that “it would be optimal to minimize travel distance between firing and counting,” the POSA would have not shared that objective. To the contrary, the POSA would have viewed that objective as both impossible and undesirable. On the one hand, the POSA would have viewed the objective of designing an inhaler and dose counter to fire and count at the same time as impossible because variations between individual devices (resulting from, for example, the manufacturing tolerances governing the sizes and shapes of their components) and their use would mean that no design could ever achieve this object. The POSA would have further understood that, even with respect to a single, individual device, the “canister fire configuration” and “count configuration” would change over time would change as a result of wear or drug deposition.

693. On the other hand, the POSA would have viewed the objective of designing an inhaler and dose counter to fire and count simultaneously would be undesirable because the firing or counting of the inhaler or dose counter could interfere unpredictably with each other. The POSA would have desired to control the environment in which the “canister fire configuration” and “count configuration” occurred as much as possible and would have understood that the actions of firing or counting would themselves disrupt that controlled environment—for example, by causing a drop in the amount of force needed to continue moving the medicament canister. The POSA would have further understood that, given the above-mentioned variations in individual devices and their use, designing an inhaler to fire and count simultaneously would result in devices that counted before firing in some cases and fired before counting in others, further undermining the POSA’s objective of maintaining a controlled environment.

694. Consequently, rather than sharing Mr. Anderson’s objective of “minimizing travel distance between firing and counting,” the POSA would have had the objective of designing a device in which the “canister fire configuration” and “count configuration” occurred reliably, which would have required maintain some minimum degree of separation between those configurations. The POSA would have been unable to predict the magnitude of this minimum separation, which could depend on variations in the manufacture or use of the individual components of the inhaler and dose counting mechanism. Without performing additional analysis of these factors, which Mr. Anderson does not even attempt to undertake, the POSA would be unable to predict whether a less than 1 mm separation between the “canister fire configuration” and “count configuration” would result in a suitable device.

695. In offering his contrary opinion, Mr. Anderson relies on a number of statements in the ’552 Publication regarding (1) the stroke lengths of certain medicament canisters; (2) the

distances between teeth in certain components; and (3) the magnitude of the force needed to actuate certain devices. *See* Anderson Opening Rep. ¶ 376 (citing '156 Patent, 11:15-18, 11:23-12:2). None of those statements, however, address the relevant issue, which is the magnitude of the minimum separation between the “canister fire configuration” and “count configuration” needed to ensure that they reliably occurred in the same order. And Mr. Anderson’s reliance on these statements further illustrates that his opinion that a less than 1 mm separation would have been obvious is based on hindsight.

696. Teva’s research and development of the claimed inventions further reflects the non-obviousness of a dose counter in which “the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.” In researching and developing the claimed inventions, the inventors conducted an extensive tolerance analysis regarding the device’s components, including the displacement of the actuator in the “canister fire configuration” and “count configuration. *See, e.g.*, TEVAQVAR-00763552 (ProAir® HFA Phase Review Presentation); TEVAQVAR-00763677 (ProAir® HFA Phase II Final Analysis Report); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); '156 Patent, 11:42-44, 17:24-61, Fig. 9, 11, 14; *supra* Section VI.B.2.a.2). Only after conducting this analysis and testing the device were the inventors able to determine that a 1 mm displacement would be suitable. That the inventors arrived at this determination only after extensive trial and error provides further evidence that the limitation would not have been obvious.

4) Claims 9 and 11-13

697. Asserted Claims 9 and 11-13 depend from Asserted Claim 1 and require, among other things, the “dose counter as claimed in claim 1” or the “dose counter of claim 1.” In my opinion, at a minimum, the '552 Publication and/or the POSA’s knowledge do not render obvious the “dose counter as claimed in claim 1” or the “dose counter of claim 1.” *See supra* Section

Section VI.B.2.a.2). Thus, the '552 Publication and/or the POSA's knowledge fail to render obvious these claims for at least these reasons.

698. Additionally, Asserted Claim 13 recites the limitation "wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister." As I explain above, this language mirrors Defendants' proposed construction of the term "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." For the reasons explained above in connection with Asserted Claim 1, the '552 Publication does not render obvious that limitation under Defendants' proposed construction. *See* Section VI.B.2.a.2)b). Thus, the '552 Publication and/or the POSA's knowledge does not render obvious Asserted Claim 13 for at least this additional reason.

b. The '406 Publication Does Not Render Obvious the Asserted Claims of the '156 Patent

699. Mr. Anderson opines that the '406 Publication renders obvious claims 1-2, 9, and 11-13. For each claim and limitation that he analyzes, Mr. Anderson repeats the assertion that if Defendants infringe the '156 Patent, then the '406 Patent necessarily renders obvious the '156 Patent because "Defendants' ANDA Products practice the invention disclosed in the '406 Publication." *See, e.g.,* Anderson Opening Rep. ¶¶ 391-399, 404, 406. I disagree. I incorporate by reference my analysis of the '406 Publication in Section IV.A as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) The POSA Would Not Have Had a Reason to Select the '406 Publication for Modification

700. As an initial matter, in my opinion, the '406 Publication does not render obvious any claim of the '156 Patent because the POSA would not have had a reason to select the '406 Publication as the basis for designing an inhaler and/or dose counter. Mr. Anderson offers no such

reason in his report. As I explain in my opinions regarding objective indicia of non-obviousness and above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined. *See* Lewis Opening Rep. §§ IX.A-B; *supra* Section VI.

701. Additionally, as I explain above in responding to Mr. Anderson's opinions relating to the '289 and '587 Patents, the '406 Publication describes five distinct dose counters that can be used in an inhaler. One dose counter is described in Paragraphs [0090]-[00116] in conjunction with Figures 1-11. A second dose counter is described in Paragraphs [00117]-[00134] in conjunction with Figures 12-20. A third dose counter is described in paragraphs [00135]-[00159] in conjunction with Figures 21-30. A fourth dose counter is described in paragraphs [00160]-[00170] in conjunction with Figures 31-40. A fifth dose counter is described in paragraphs [00171]-[00182] in conjunction with Figures 41-47. *See supra* Section VI.A.1.a.1)a).

702. Mr. Anderson's opinions that the '406 Publication renders obvious the Asserted Claims of the '156 Patent mix and match various disclosures from these five separate examples indiscriminately, without identifying any reason why the POSA would have done so. I do not agree with this approach, because the '406 Publication describes these embodiments as different dose counters, and the POSA would not understand a feature of one to be interchangeable with a feature of another. If anything, the disclosure of five distinct dose counters, none of which individually embodies the claimed inventions, reinforces the validity of the Asserted Claims.

2) Claim 1

703. Additionally, in my opinion, the '406 Publication does not render obvious any Asserted Claim 1 of the '156 Patent (and, therefore, does not render obvious any Asserted Claim) because it does not render obvious multiple limitations in Asserted Claim 1.

704. Among other things, Asserted Claim 1 of the '156 Patent requires the actuator to be “arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.” Asserted Claim 1 further requires that “in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.”

705. In my opinion, the '406 Publication does not provide any information that would have given the POSA a reason to develop an inhaler and dose counter that satisfied those limitations with a reasonable expectation of success. To the contrary, based on the '406 Publication's two-dimensional disclosures, the POSA would not understand the '406 Publication to disclose and/or render obvious these limitations and, therefore, would not understand to anticipate and/or render obvious any of the other claims. For example, the '406 Publication does not describe the sequence of configurations that the devices that it discloses undergo before they count and/or fire. The '406 Publication also does not describe the position of the “actuator pawl” relative to a “shoulder of the valve stem block” at any point in those devices' operation. This information cannot be deduced from the '406 Publications descriptions and figures—the POSA would need data regarding the coordinates and/or dimensions of the locations of the various components that it describes, and it provides no such data.

706. Indeed, to determine whether Defendants' ANDA Products satisfy those limitations, I conducted a series of experiments on physical samples of Defendants' ANDA

Products in which I measured the positions of the Defendants’ actuator pawls (i.e., one or more of the protrusions on the bottom of what Defendants refer to as an “indexer”) during the devices’ operation. *See* Lewis Opening Reps. §§ VIII.C.1.e-g. Based on that analysis, I concluded that Defendants’ ANDA Products did, in fact, satisfy them. *See* Lewis Opening Reps. §§ VIII.C.1.e-g. The ’406 Publication provides no such information with respect to any of the embodiments it discloses.

707. In addition to the insufficiency of the ’406 Publication’s disclosures, in my opinion, the POSA would have avoided developing an inhaler and dose counter that satisfied the limitations of Asserted Claim 1 and would have expected that such an inhaler and dose counter would fail. As I explain above, the POSA would have avoided developing a device in which the “canister fire configuration” occurred before the “count configuration.” *See supra* Section VI.B.2.a.2)a). The POSA further would also have avoided making modifications to the positioning of the “actuator pawl” such that it would result in a device in which the “actuator pawl” was “below a datum plane which passes through a shoulder of the valve stem block.” *See supra* Section VI.B.2.a.2)a). In both the cases, the POSA would have expected that such modifications would result in an unsuitable device. *See supra* Section VI.B.2.a.2)a). Moreover, even were the POSA to undertake such an effort (which in my opinion, the POSA would not have done), the POSA would have needed to test a large and unpredictable number of potential solutions, consisting of variations in the design and position of the components of the inhaler or dose counting mechanism, without knowing which of those might succeed. Mr. Anderson’s opinions that the ’406 Publication nonetheless discloses and/or renders obvious these limitations are based entirely on unsupported conjecture.

3) Claim 2

708. Claim 2 of the ’156 Patent depends from Asserted Claim 1 and recites: “A dose

counter as claimed in claim 1 in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.” In my opinion, at a minimum, the ’406 Publication and/or the POSA’s knowledge do not render obvious the “dose counter as claimed in claim 1.” *See supra* Section VI.B.2.b.2). Additionally, in my opinion, the ’406 Publication and/or the POSA’s knowledge do not render obvious a dose counter “in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.” The ’406 Publication provides no such measurements; nor can they be inferred. Additionally, the POSA would not have had a reason to develop such a dose counter with a reasonable expectation of success, *see supra* Section VI.B.2.a.3), and the ’406 Publication alone or in combination with the POSA’s knowledge provides no such reason or expectation. Thus, the ’406 Publication and the POSA’s knowledge fail to render obvious this claim.

4) Claims 9 and 11-13

709. Asserted Claims 9 and 11-13 depend from Asserted Claim 1 and require, among other things, the “dose counter as claimed in claim 1” or the “dose counter of claim 1.” In my opinion, at a minimum, the ’406 Publication and/or the POSA’s knowledge do not render obvious the “dose counter as claimed in claim 1” or the “dose counter of claim 1.” *See supra* Section VI.B.2.b.2). Thus, the ’406 Publication and/or the POSA’s knowledge fail to render obvious these claims for at least these reasons.

710. Additionally, Asserted Claim 13 recites the limitation “wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister.” As I explain above, this language mirrors Defendants’ proposed construction of the term “datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.” For the reasons explained above in connection with Asserted Claim 1, the ’406 Publication does not disclose and/or render obvious

that limitation under Defendants’ proposed construction. *See supra* Section VI.B.2.b.2). Thus, the ’406 Publication and/or the POSA’s knowledge fail to render obvious Asserted Claim 13 for at least this additional reason.

* * *

711. In sum, I disagree with Mr. Anderson’s conclusions that the Asserted Claims would have been obvious, including based on the references and supposed knowledge that he describes in his reports. However, even if Mr. Anderson could show that the Asserted Claims would have been obvious in view of those arguments, in my opinion, strong objective indicia of non-obviousness establish that the claims are not invalid. *See* Lewis Opening Reps. § IX.

712. I further note that the ’552 Publication was before the examiner during prosecution of the ’156 Patent. *See, e.g.*, ’156 Patent, Foreign Patent Documents. I have conducted an independent analysis of the ’552 Publication, and in my opinion, the ’552 Publication does not render obvious the Asserted Claims, alone or in combination with the purported knowledge that Mr. Anderson describes. The fact that the examiner made similar determinations as to each of these claims provides further evidence that the ’552 Publication does not render obvious those claims.

3. Asserted Claim 12 of the ’156 Patent Is Not Indefinite

713. Mr. Anderson opines that Asserted Claim 12 of the ’156 Patent is structurally impossible and indefinite because the phrase “the body,” which appears in Asserted Claims 1, 11, and 12, is used “inconsistently throughout these claims.” *See* Anderson Opening Rep. § XVI.D. Specifically, Mr. Anderson opines the phrase “the body” refers to the inhaler “body” each time that it is used in the claims. *See* Anderson Opening Rep. ¶¶ 408-411. Mr. Anderson opines that Asserted Claim 12 is structurally impossible and indefinite because (based on his assumption that the term “body” refers to the “body of the inhaler” throughout the claim) “the ‘body of the inhaler’

cannot be located inside of the counter chamber that is, in turn, located in the ‘body of the inhaler.’” Anderson Opening Rep. ¶ 411. I disagree with Mr. Anderson. In my opinion, the POSA would understand with reasonable certainty the scope of the claimed inventions. Mr. Anderson’s contrary opinion ignores or misinterprets the relevant aspects of the claim language, specification, and prosecution history, each of which confirms that Asserted Claim 12 is not structurally impossible or indefinite.

714. Asserted Claims 1, 11, and 12 recite as follows. As shown below, the word “body” appears once in each of Asserted Claims 1 and 11 and three times in Asserted Claim 12. I have **bolded, italicized, and underlined** these usages. For reference, I have also numbered Asserted Claim 12’s three usages of the phrase “the body.”

715. Asserted Claim 1 recites:

1. A dose counter for a metered dose inhaler having a **body** arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
a ratchet wheel having a plurality of circumferentially spaced teeth,
an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate,
the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
a dosage indicator associated with the count pawl, wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth, wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a

canister fire configuration,
the medicament canister fires medicament before the dose
counter reaches a count
configuration, and when the actuator is in a third position after
the second position, the
count pawl resiliently jumps over the second tooth and the dose
counter reaches the count
configuration, whereby the dosage indicator has indicated a
count,
wherein, in the canister fire configuration, the actuator
pawl is below a datum plane which passes through a shoulder of
a valve stem block
configured to receive the medicament canister.⁴

716. Asserted Claim 11 depends from Asserted Claim 1 and recites: “An inhaler comprising the **body** arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1.”

717. Asserted Claim 12 depends from Asserted Claim 11 and recites: “An inhaler as claimed in claim 11 in which **[1] the body** includes a canister-receiving portion and a separate counter chamber; **[2] the body**, ratchet wheel and actuator being located inside the counter chamber, **[3] the body of the inhaler** having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.”

718. I have been informed that the parties have proposed that the term “the body” in Asserted Claim 12 should be construed as follows:

No.	Claim Term	Teva’s Construction	Defendants’ Construction
10	“the body”	Plain and ordinary meaning in view of the claims,	This term is indefinite.

⁴ I note that Mr. Anderson reproduces only a heavily excerpted portion of Asserted Claim 1. See Anderson Opening Rep. ¶ 408. That excerpting is consistent with Mr. Anderson’s failure to properly consider the full context in which the phrase “the body” appears.

	'156 Patent, claim 12	specification, and prosecution history. <u>[1, 3]</u> “inhaler body” - '156 Patent, 22:64, 67 <u>[2]</u> “dose counter body” - '156 Patent, 22:66	
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719. In my opinion, the POSA would understand with reasonable certainty that the phrase “the body” in Asserted Claim 12 referred to different components of the inventions, based on the context in which the term was used. The POSA would understand that the first and third usages of the phrase “the body” referred to the inhaler “body” and that the second usage referred to the dose counter “body.” The POSA would reject Mr. Anderson’s conclusion that the term “the body” was structurally impossible or indefinite. As I describe below and throughout in greater detail, the POSA would reach these conclusions based on each of the claim language, specification, and prosecution history, alone and as informed by his or her knowledge.

720. **Claim Language.** With respect to Asserted Claim 12’s first usage of the phrase “the body,” the POSA would note that the claim language states: “An inhaler as claimed in claim 11 in which [1] the body includes a canister-receiving portion and a separate counter chamber.” The POSA would understand that because this phrase refers to the “inhaler,” “the body” must refer to the inhaler “body.” In addition, the POSA would note that Asserted Claims 1 and 11, from which Asserted Claim 12 depends, state that the inhaler “body” is “arranged to retain a medicament canister of predetermined configuration. The POSA would understand the limitation requiring “the body” to include “a canister-receiving portion and a separate counter chamber” to accord with that meaning.

721. With respect to Asserted Claim 12’s second usage of the phrase “the body,” the POSA would note that the claim language states: “[2] the body, ratchet wheel and actuator being

located inside the counter chamber.” The POSA further would note that Asserted Claim 1, from which Asserted Claim 12 depends (via Asserted Claim 13), refers to a “dose counter” comprising a “ratchet wheel” and “actuator.” Because Asserted Claim 12 refers to the “the body, ratchet wheel and actuator” together, the POSA would understand the phrase “the body” to likewise refer to a component of the dose counter—i.e., the dose counter “body.”

722. With respect to Asserted Claim 12’s third usage of the phrase “the body,” the POSA would note that the claim language states: “[3] the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber.” Thus, the POSA would understand that the third usage, like the first usage,” refers to the inhaler “body.” The POSA would further understand the claim’s usage of the complete phrase “the body of the inhaler” to be evidence that the second and third usages referred to different components—further confirming that the second usage referred to the dose counter “body.”

723. Mr. Anderson opines that Asserted Claim 12’s second usage of the term “the body” is structurally impossible or indefinite because the POSA would understand it to refer the inhaler “body.” Anderson Opening Rep. ¶ 311. I disagree. In my opinion, Mr. Anderson’s analysis is contrary to the approach that the POSA would have taken in understanding the claim language. Mr. Anderson appears to assume that the phrase “the body” to have the same meaning each time that it was used and, then, based on that assumption, asserts that Asserted Claim 12 is structurally impossible. Anderson Opening Rep. ¶ 311. By contrast, the POSA would have understood that common terms, such as “body,” could have different meanings based on the contexts in which they were used, and, based on those contexts, would select the appropriate ones. Following those principles, the POSA would understand that the second usage of the term “the body” must refer to the dose counter “body,” in part, because the contrary conclusion would yield a nonsensical result.

724. In connection with his opinions on anticipation and obviousness, Mr. Anderson states his understanding that “Plaintiffs have proposed a construction rewriting this claim [i.e., Asserted Claim 12] in an attempt to preserve validity” or similar. *See* Anderson Opening Rep. ¶¶ 352, 383, 403. I do not know how Mr. Anderson formed this understanding, but I disagree with the assertion that my understanding of the claim involves a “rewriting” of the claim language “to preserve validity.” Frequently, my colleagues and I in the inhalation aerosol industry are confronted by multiple usages of the same term, for example, in scientific or technical papers or presentations, which, if understood to have a single meaning, would render those usages non-sensical. In such cases, however, the approach that my colleagues and I take (and the one that the POSA would take here) is to afford language its sensible meaning in the context in which it appears. That is not a “rewriting,” and we are certainly not concerned with preserving the “validity” of those statements. Rather, it is the ordinary approach that we take in interpreting the statements made by others. We do not assume that, because there are multiple usages, they must mean the same thing, regardless of whether that meaning would be sensible.

725. **Specification.** The POSA would note that the specification provides further evidence that the phrase “the body” in Asserted Claim 12 should be understood in the manner described above. For example, the POSA would note that, consistent with Asserted Claim 12’s first and third usages of the phrase “the body” to refer to the inhaler “body,” the specification states that the “inhaler main body may include a canister receiving portion and a separate counter chamber, the dose counter being located within the main body thereof, the incremental output member and actuator thereof inside the counter chamber.” ’156 Patent, 60:20-33.

726. Additionally, the POSA would note that, consistent with Asserted Claim 12’s second usage of the phrase “the body” to refer to the dose counter “body,” the specification states

that “dose counter” comprises “an incremental counting system for counting doses,” which has “a main body,” an “actuator,” and an “incremental output member.” ’156 Patent, 4:46-65. The POSA would further note that, in certain embodiments, the specification refers to the “incremental output member” as a “ratchet wheel.” ’156 Patent, 5:22-25. This would further confirm to the POSA that Asserted Claim 12’s second usage of the phrase “the body” in parallel with the “ratchet wheel” and “actuator” was meant to refer to the dose counter “body.”

727. To support his contrary opinions, Mr. Anderson offers the following statements regarding the ’289 Patent’s specification (which is similar to the ’156 Patent’s specification):

I understand that Plaintiffs have argued that “the body” merely lacks antecedent basis (e.g., it was not properly introduced earlier in the claim) and was intended to refer to a different body—specifically the body of the dose counter. However, nothing in the claims or specification would lead a person of skill in the art to that conclusion. The specification describes of number of “bodies” including “main body of the dose counter” (’289 Patent at 3:13, 3:51-52, 10:50-51); “main body of the incremental count system” (*id.* at 6:46, 10:43, 11:11-12, 11:18, 11:30, 12:31, 14:23, 16:6-7, 17:14-15); body for retaining a medicament store (*id.* at 7:28, 7:63); “the main canister body” (*id.* at 9:19-21); “inhaler main body” (*id.* at 6:24, 10:36-37, 11:19, 11:24-25, 11:33-34, 12:31); and “actuator body” (*id.* At 1:33-34). In fact, the term “body” appears over 70 times. Moreover, a person of skill in the art would have no reason to attempt to guess at what was intended, when the claims themselves already clearly defined body. The mere fact that the claim was written poorly, such that it is inoperable and indefinite, does not change the fact that “the body” was clearly defined in the claims. Even if a POSA were to attempt to speculate on which other “body” may have been intended, the number of different “bodies” described in the specification and the frequency in which the term is used prohibits a POSA from making that determination with any confidence.

Anderson Opening Rep. ¶ 412.⁵

⁵ I have been informed that Mr. Anderson’s reference to “antecedent basis” refers to a practice in patent law of referring to a claim term using an indefinite article (e.g., “a”) the first time that it is used and a definite article (e.g., “the,” “said”) thereafter. In my opinion, the fact that Asserted

728. I disagree with Mr. Anderson's discussion of the specification. That the specification "describes of number of 'bodies'" is immaterial. What would matter to the POSA is not whether the specification "describes of number of 'bodies,'" but rather how the specification's usages of the phrase "the body" could be used to inform his or her understanding of the claim language. Significantly, Mr. Anderson's discussion of the specification contains no comparisons between the specification's usages of "the body" and Asserted Claim 12's usages of that phrase. As I explain above, the descriptions in the specification that the POSA would find to be most relevant (i.e., those that most closely resemble the claim language) would further confirm to the POSA that Asserted Claim 12's first and third usages of the phrase "the body" refer to the inhaler "body" and its second usage refers to the dose counter "body."

729. **Prosecution History.** In addition to analyzing the claim language and specification, the POSA would note that the examiner allowed Asserted Claims 1, 11, and 12, without expressing any uncertainty about the meaning of the term "body." *See, e.g.*, TEVAQVAR-00022932, at -24936-43. I recognize that the fact that the examiner did not issue an indefiniteness rejection as to that term is not necessarily decisive. However, it provides further evidence that the POSA would have understood with reasonable certainty the scope of the claimed inventions and that Defendants' contrary position is based on an improper effort to manufacture ambiguity where none, in fact, exists.

C. The '808 Patent

1. Mr. Anderson's Anticipation Theories Are Incorrect

Claim 12 refers to "the body" using the indefinite article would not prevent the POSA from understanding with reasonable certainty the meaning of that phrase in view of the other evidence cited in my report.

a. The '552 Publication Does Not Anticipate Asserted Claim 1 of the '808 Patent

730. Mr. Anderson opines that the '552 Publication anticipates Asserted Claim 1 of the '808 Patent. *See* Anderson Opening Rep. § XVII.A. I disagree. In my opinion, the POSA would not understand that the '552 Publication discloses the limitations of Asserted Claim 1 as arranged in that claim. I incorporate by reference my analysis of the '552 Publication in Section IV.B as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) Claim 1

731. Asserted Claim 1 recites as follows:

1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

732. I have been informed that the parties have agreed upon constructions for the terms “regulator,” “regulate motion of the counter display,” and “first direction.” *See supra* Section III.B. I have applied those constructions in performing my analysis.

733. I further have been informed that the parties have proposed different constructions for the terms “counter display arranged to indicate dosage information,” “first station,” and “second station.”

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
11	“counter display arranged to indicate dosage information” '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a component of the dose counter that displays information regarding the	“structure displaying the number of doses remaining”

<u>No.</u>	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
		number of doses remaining	
12	"first station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a first region"	"first structure on which the counter is located"
13	"second station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a second region"	"second structure, separate from the first structure, to which the counter display is moved"

734. I have not been asked to provide an opinion as to which proposed constructions are correct, and I express no opinion on that issue. In my opinion, the '552 Publication does not anticipate Asserted Claim 1 of the '808 Patent under any proposed construction.

a) The '552 Publication Does Not Disclose the Limitations of Asserted Claim 1 of the '808 Patent as Arranged in That Claim

735. As an initial matter, in my opinion, the '552 Publication does not anticipate Asserted Claim 1 of the '808 Patent because the '552 Publication does not disclose the limitations of Asserted Claim 1 as arranged in the claim. I have been informed that "anticipation" requires that every element of the claims appear in a single reference. Notably, in asserting his anticipation argument with respect to the '552 Publication, Mr. Anderson relies on descriptions and figures across multiple references—*i.e.*, both the '552 Publication and the '950 Publication. *See* Anderson Opening Rep. ¶¶ 430-32. Moreover, as I explain above in connection with the '156 Patent, Mr. Anderson's analysis of the '552 Publication mixes and matches disclosures from multiple embodiments within that publication, which the POSA would understand to be separate. *See supra* Section VI.B.1.a.1). Mr. Anderson's reliance across multiple references, and multiple disclosures within those references, undermines his conclusion that the '552 Publication anticipates Asserted

Claim 1 of the '808 Patent and provides further evidence that his opinions are driven by hindsight.

b) The '552 Publication Does Not Disclose the Regulator Limitation

736. Additionally, in my opinion, the '552 Publication does not anticipate Asserted Claim 1 of the '808 Patent because it does not disclose the limitation “wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.”

737. Among other things, Asserted Claim 1 requires the “regulator” to “modulate motion of the counter display” to “incremental movements.”

738. Mr. Anderson asserts that the '552 Publication “discloses a regulator—forks inside the tape stock bobbin—regulating the motion of the display to incremental movements” based on a flawed analysis of Figure 6 of the '552 Publication. Anderson Opening Rep. ¶¶ 427, 429 (citing '552 Publication, 9:9-18, Fig. 6). I reproduce Figure 6 below:

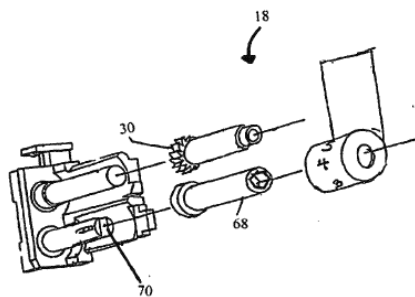


Fig. 6

739. To support his opinion, Mr. Anderson states that, in this figure, the “dose counter 18 . . . is held taut by the action of the split hub 70,” Anderson Opening Rep. ¶ 429 (quoting '552 Publication, 9:9-12), and that what he refers to as the “protrusion” shown in Figure 6 of the '552 Publication “is essentially identical to the protrusion shown in Figure 6A[—an embodiment—]of the '808 patent,” Anderson Opening Rep. ¶ 429.

740. Mr. Anderson provides a marked-up version of Figure 6 of the '552 Publication in

which he identifies the “protrusion” using a red circle. I reproduce Mr. Anderson’s marked-up version of that figure below:

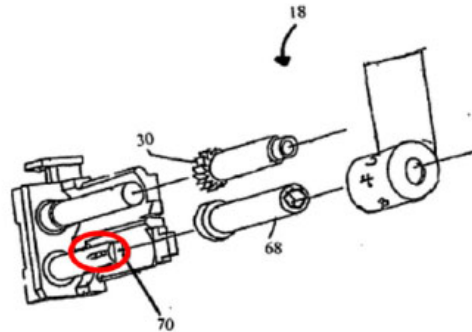


Fig. 6

See Anderson Opening Rep. ¶ 429.

741. Mr. Anderson states that:

Stock Bobbin 68 of the '552 Publication, like stock bobbin 110 of the '808 Patent, is shaped irregularly, like a hexagon at the entrance to the bobbin. Although the '552 Publication does not explicitly recite the purpose of the protrusions of the split hub, it is apparent that its purpose is to contact the interior of the stock bobbin 68, and modulate motion of the tape to prevent unwanted unrolling (e.g., to modulate it to incremental movement). This is confirmed by the '950 Publication, which is directed to a dose counter with the same split hub, same protrusions 146, and same stock bobbin 132. See '950 Publication at Fig. 15. The '950 Publication refers to these protrusions as “radially nubs for creating resilient resistance to rotation of the bobbin 132 on the shaft 142.” *Id.* at [0057].

Anderson Opening Rep. ¶ 430.

742. Based on this analysis, Mr. Anderson asserts “that the protrusion disclosed in Figure 6 of the '552 Publication is a ‘regulator’ that is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements is confirmed by the '950 Publication.” Anderson Opening Rep. ¶ 431. I disagree with Mr. Anderson.

743. As an initial matter, as I explain above, the '552 Publication and '950 Publication

are separate references, which the POSA would not understand to be part of the same disclosure. *See supra* Section VI.C.1.a.1)a). Mr. Anderson's reliance on the '950 *Publication* to support his opinion that the '552 *Publication* anticipates Asserted Claim 1 of the '808 Patent provides further evidence that the '552 *Publication* does not, in fact, disclose the limitations of that claim.

744. Regardless, even if Mr. Anderson's anticipation analysis were correct (which in my opinion, it is not), his analysis of the '552 *Publication* (and '950 *Publication*) is flawed. During prosecution of the application that issued as the '808 Patent, the Board rejected arguments that are indistinguishable from the opinions that Mr. Anderson offers here. Specifically, the Board found that the '950 *Publication* did not render unpatentable the regulator limitation based on analysis of the same disclosures that Mr. Anderson relies upon to support his opinions. *See* '808 Patent File History, Board Decision (Sept. 20, 2019). I have been informed that the Board's opinions are not dispositive of validity, and I have performed my own independent analysis of those disclosures. Nevertheless, in my opinion, the fact that an experienced agency reached the same conclusion provides further evidence that Mr. Anderson is incorrect.

745. In reversing the examiner's rejection of the pending claims over the '950 *Publication*, the Board recognized that Asserted Claim 1 of the '808 Patent "requires a regulator capable of 'regulat[ing] motion of the counter display at the first station to incremental movements.'" '808 Patent File History, Board Decision 4 (Sept. 20, 2019) (citation omitted). The Board explained that the '950 *Publication* contains no evidence that the embodiments it discloses are "capable of such regulated motion." '808 Patent File History, Board Decision 5 (Sept. 20, 2019). In particular, the Board stated:

[The '950 *Publication*] is ambiguous [on] whether or not bobbin 132 necessarily has complementary features to match the nubs of shaft 142. As [the patentees] explain[], [the '950 *Publication*] merely teaches that its nubs serve to "creat[e] a resilient resistance to

rotation of the bobbin 132 on the shaft 142” ([950 Publication at ¶ [0057]) and the nubs could serve this purpose without having complementary features. . . . While [the ’950 Publication’s] Figure 15 depicts a hexagonal opening to bobbin 132, it is unclear whether this hexagonal structure continues into the interior of bobbin 132 or engages with nubs 146.

’808 Patent File History, Board Decision 5 (Sept. 20, 2019).

746. The Board made clear that:

even if the evidence adequately supported that [the ’950 Publication] nubs 146 interact with the hexagonal structure or some other corresponding structure of bobbin 132, it is not clear that the interaction would . . . necessarily result in incremental movements. . . . [T]he Examiner fails to establish that a person of skill in the art would have reached a regulator capable of regulating motion in the manner claim 1 recites based upon the teachings of [the ’950 Publication] or otherwise.

’808 Patent File History, Board Decision 5 (Sept. 20, 2019).

747. I have independently reviewed the ’950 Publication and the Board’s decision, and I agree with the Board. In my opinion, nothing in the ’950 Publication discloses a regulator that is capable of regulating the motion of the counter display to incremental movements, as Asserted Claim 1 of the ’808 Patent requires. For example, as the Board found, ’950 Publication does not suggest that the bobbin in the ’950 Publication’s dose counter has complementary features that match the radial axial nubs of the shaft. Nor does anything in the ’950 Publication suggest that the bobbin and shaft—or any other combination of components—interact to regulate the motion of a counter display to incremental movements via any other mechanism.

748. Moreover, the Board’s analysis regarding the ’950 Publication applies with equal force to the ’552 Publication. As with the examiner’s analysis of the ’950 Publication, which the Board rejected, Mr. Anderson’s analysis of the ’552 Publication relies on the interaction between the ’552 Publication’s stock bobbin and split hub. Like the ’950 Publication, the ’552 Publication

does not suggest that the stock bobbin in its dose counter has complementary features that match the features on the split hub or otherwise disclose or suggest anything that regulates the motion of the counter display to incremental movements. I therefore disagree with Mr. Anderson's analysis.

749. To support his contrary opinions, Mr. Anderson relies on the '552 Publication's reference to a "dose counter 18 which is held taut by the action of the split hub 70." Anderson Opening Rep. ¶ 429 (quoting '552 Publication, 9:9-12). Mr. Anderson's reliance on that statement is misplaced. Nothing in that statement or elsewhere in the '552 Publication suggests that split hub 70 modulates the motion of the counter display to *incremental* movements, as Asserted Claim 1 of the '808 Patent requires. Instead, as the '552 Publication discloses and Mr. Anderson acknowledges, the '552 Publication merely states that the split hub in this particular embodiment creates tension and resist unwanted movement in the stock bobbin 68, on which the counter 44 is mounted. *See* '552 Publication, 10:6-8. Nothing in the '552 Publication suggests that the dose counter moves incrementally, much less that the split hub in this embodiment has any effect in achieving that outcome. To the contrary, the POSA would understand the '552 Publication's emphasis on the split hub's maintaining tension to mean that it resists movement generally—not incrementally, as Asserted Claim 1 requires.

750. Moreover, a comparison of the examples in the '808 Patent and '552 Publication supports the conclusion that they do not function in the same manner. Although Mr. Anderson asserts that Figure 6 of the '552 Publication and Figure 6A of the '808 Patent are "essentially identical," Anderson Opening Rep. ¶ 429, the evidence actually supports the opposite. To wit, the '808 Patent states that, in certain embodiments, the regulator comprises "a wavelike engagement surface with concavities which engage against the control elements in the form of protrusions on resilient forks of a split pin." '808 Patent, 4:45-48. Figure 6F of the '808 Patent describes control

elements 128 and 130 on the resilient fork of the dose counter:

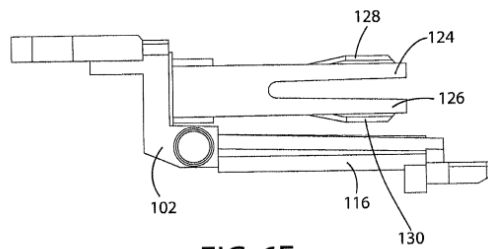


FIG. 6F

'808 Patent, Fig. 6F, 18:8.

751. In addition, Figure 15 of the '808 Patent discloses a tape stock bobbin that comprises "an inwardly facing generally cylindrical engagement surface 300 with a wavelike form extending partially therealong. The engagement surface 300 has a cross-section perpendicular to the longitudinal length of the stock bobbin":

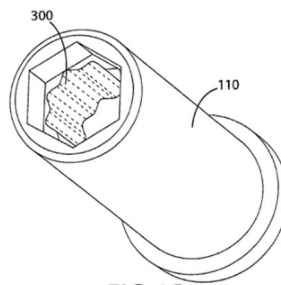


FIG. 15

'808 Patent, Fig. 15, 18:12-17.

752. The '552 Publication discloses no such features or anything that would be expected to function in the same manner. Nothing in the '552 Publication suggests that the interaction between the stock bobbin and the split hub modulates the movement of the counter display to incremental movements, as Asserted Claim 1 of the '808 Patent requires, including, for example, by suggesting that the bobbin has complementary features to match the nubs of the split hub in Figure 6. By way of further example, nothing in the '552 Publication suggests that the hexagonal structure of the bobbin continues into the interior of the bobbin or engages with the nubs of the

split hub. Nor does any disclosure of the '552 Publication discuss any such features. The '552 Publication is largely silent on the features of the split hub and the bobbin.

753. Mr. Anderson acknowledges that the '552 Publication fails to “recite the purpose of the protrusions on the split hub.” Anderson Opening Rep. ¶ 430. Nevertheless, he asserts in conclusory fashion that the purpose of the protrusion(s) are “to contact the interior of the stock bobbin 68, and modulate the motion of the tape to prevent unwanted rolling (e.g., *to modulate it to incremental movement*).” Anderson Opening Rep. ¶ 430 (emphasis added). But nothing in the '552 Publication shows that the protrusion on the split hub or the split hub itself would modulate the motion of the counter display to *incremental* movements, as Asserted Claim 1 of the '808 Patent requires. Rather, Figure 6 of the '552 Publication, which purports to show the dose counter within the body of the inhaler, clearly shows the absence of a regulator.

754. To be clear, I do not suggest that the only way to achieve a regulator is via the interaction of the nubs on the split hub and a wavelike engagement surface with concavities on the stock bobbin which engage the nubs on the split hub. But Mr. Anderson has failed to identify any additional aspects of these prior art references that could serve as a regulator.

755. The '808 Patent itself provides additional evidence that the POSA would not have understood the tape stock bobbin/split hub combination disclosed in the '552 Publication or the radial axis nubs disclosed in the '950 Publication to regulate the counter display to incremental movements. The '808 Patent expressly acknowledges the '552 Publication's prior description of a device comprising “a split pin intended to hold the stock bobbin taut,” but distinguishes the '552 Publication and other prior art devices on the ground that such mechanisms were inadequate to prevent the dose counter from counting, if for example, such devices were “dropped on a hard surface.” '808 Patent, 2:5-40. The '808 Patent describes that the “regulator is advantageous in

that it helps prevent unwanted motion of the counter display if the counter is dropped.” ’808 Patent, 2:54-56. Consistent with the ’808 Patent’s descriptions, the POSA would understand that the ’552 Publication not to disclose such a “regulator.”

756. Teva’s documents further confirms that the ’552 Publication does not disclose a “regulator.” Specifically, before Teva implemented one embodiment of a “regulator” (as set forth in the ’808 Patent) in its inhalers, Teva unexpectedly found that continuous or frictional resistance like that provided by a stock bobbin/split hub combination and/or radial axis nubs like those disclosed in the ’552 Publication or ’950 Publication did not modulate the counter display to incremental movements. *See, e.g.*, TEVAQVAR-00737016, at -7016-018; TEVAQVAR-00032306; TEVAQVAR-00032308; *see also* TEVAQVAR-00734380; TEVAQVAR-00734383. Teva noticed that the counter display in its inhalers was moving even without a user actuating the device. *See id.* As that history demonstrates, continuous or frictional resistance like that provided by the tape stock bobbin/split hub combination disclosed in the ’552 Publication and/or radial axis nubs disclosed in the ’950 Publication does not necessarily modulate the counter display to incremental movements, as Asserted Claim 1 of the ’808 Patent requires, and the POSA would not have understood such a combination to do so.

757. In sum, it is my opinion that the ’552 Publication does not anticipate Asserted Claim 1 of the ’808 Patent.

b. The ’950 Publication Does Not Anticipate Asserted Claim 1 of the ’808 Patent

758. Mr. Anderson asserts that the ’950 Publication anticipates Asserted Claim 1 of the ’808 Patent. *See* Anderson Opening Rep. § XVII.C. I disagree. In my opinion, the POSA would not understand that the ’950 Publication discloses the limitations of Asserted Claim 1 as arranged in that claim. I incorporate by reference my analysis of the ’950 Publication in Section IV.F as

though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) Claim 1

a) The '950 Publication Does Not Disclose the Limitations of Asserted Claim 1 of the '808 Patent as Arranged in That Claim

759. As an initial matter, the '950 Publication does not anticipate Asserted Claim 1 of the '808 Patent because the '950 Publication does not disclose the limitations of Asserted Claim 1 as arranged in the claim. Throughout his analysis of the '950 Publication, Mr. Anderson relies on various descriptions and figures in the '950 Publication, without explaining why the POSA would have focused on those disclosures or treated them as a single disclosure or embodiment. *See* Anderson Opening Rep. ¶¶ 440-50. Mr. Anderson's failure to provide such an explanation provides further evidence that his opinions are driven by hindsight.

b) The '950 Publication Does Not Disclose the Regulator Limitation

760. Additionally, in my opinion, the '950 Publication does not anticipate Asserted Claim 1 of the '808 Patent because it does not disclose the limitation “wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.”

761. Among other things, Asserted Claim 1 requires the “regulator” to “modulate motion of the counter display” to “incremental movements.”

762. Mr. Anderson asserts that the '950 Publication “discloses a regulator—forks inside the tape stock bobbin—regulating the motion of the display to incremental movements” based on a flawed analysis of Figure 15 of the '950 Publication. Anderson Opening Rep. ¶¶ 445-46 (citing '950 Publication, [0057], Fig. 15). I reproduce Figure 15 below:

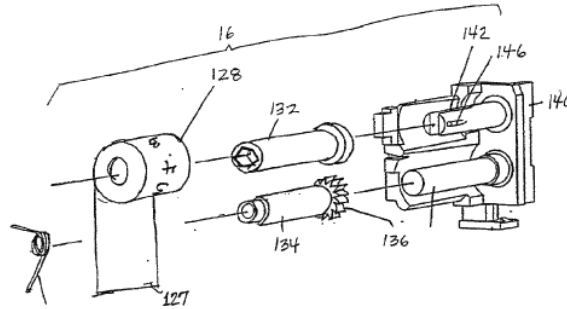


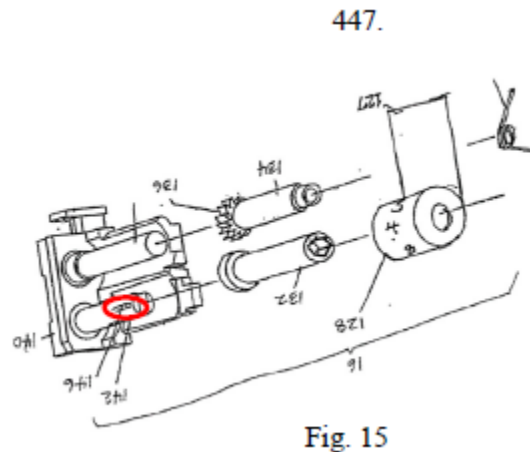
FIG. 15

763. To support his opinion, Mr. Anderson states that:

Figure 15 of the '950 Publication, discloses a dose counter display system 16 which includes a bobbin 132 and an indexing spool 134 that are mounted on shafts 142 and 144, respectively. The bobbin shaft 142 is forked and includes radially extending nubs 146 that are described by the '950 Publication as “creating a resilient resistance to rotation of the bobbin 132 on the shaft 142.”

Anderson Opening Rep. ¶ 445.

764. Mr. Anderson provides a marked-up version of Figure 15 of the '950 Publication in which he identified the “radially extending nubs” using red circle. I reproduce Mr. Anderson’s marked-up version of that figure below:



See Anderson Opening Rep. ¶ 446.

765. Mr. Anderson states that “the ‘radially extending nubs’ shown in Figure 15 of the

'950 Publication . . . are essentially identical to the protrusion shown in Figure 6A of the '808 Patent . . . , and are even located in the same location on the forked bobbin shaft.” Anderson Opening Rep. ¶ 446.

766. As I explain above (*see supra*, Section VI.C.1.a.1)b)), the Board considered and rejected arguments similar to those Mr. Anderson presents here. *See* '808 Patent File History, Board Decision (Sept. 20, 2019). Specifically, the Board found that the '950 Publication did not render unpatentable the regulator limitation based on analysis of the same disclosures that Mr. Anderson relies upon to support his opinions. *See* '808 Patent File History, Board Decision (Sept. 20, 2019). I have been informed that the Board's opinions are not dispositive of validity, and I have performed my own independent analysis of those disclosures. Nevertheless, in my opinion, the fact that an experienced agency reached the same conclusion provides further evidence that Mr. Anderson is incorrect.

767. In reversing the examiner's rejection of the pending claims over the '950 Publication, the Board recognized that Asserted Claim 1 of the '808 Patent “requires a regulator capable of ‘regulat[ing] motion of the counter display at the first station to incremental movements.’” '808 Patent File History, Board Decision 4 (Sept. 20, 2019) (citation omitted). The Board explained that the '950 Publication contains no evidence that the embodiment it discloses are “capable of such regulated motion.” '808 Patent File History, Board Decision 5 (Sept. 20, 2019). In particular, the Board stated:

[The '950 Publication] is ambiguous [on] whether or not bobbin 132 necessarily has complementary features to match the nubs of shaft 142. As [the patentees] explain[], [the '950 Publication] merely teaches that its nubs serve to “creat[e] a resilient resistance to rotation of the bobbin 132 on the shaft 142” ([950 Publication at ¶ [0057]) and the nubs could serve this purpose without having complementary features. . . . While [the '950 Publication's] Figure 15 depicts a hexagonal opening to bobbin 132, it is unclear whether

this hexagonal structure continues into the interior of bobbin 132 or engages with nubs 146.

'808 Patent File History, Board Decision 5 (Sept. 20, 2019).

768. The Board made clear that:

even if the evidence adequately supported that [the '950 Publication] nubs 146 interact with the hexagonal structure or some other corresponding structure of bobbin 132, it is not clear that the interaction would . . . necessarily result in incremental movements. . . . [T]he Examiner fails to establish that a person of skill in the art would have reached a regulator capable of regulating motion in the manner claim 1 recites based upon the teachings of [the '950 Publication] or otherwise.

'808 Patent File History, Board Decision 5 (Sept. 20, 2019).

769. As I stated above, I have independently reviewed the '950 Publication and the Board's analysis. In my opinion, a comparison of the examples in the '808 Patent and '950 Publication supports the conclusion that they do not function in the same manner. Although Mr. Anderson asserts that Figure 15 of the '950 Publication and Figure 6A of the '808 Patent are "essentially identical," Anderson Opening Rep. ¶ 446, the evidence supports the opposite. The '808 Patent states that, in certain embodiments, the regulator comprises "a wavelike engagement surface with concavities which engage against the control elements in the form of protrusions on resilient forks of a split pin." '808 Patent, 4:45-48. Figure 6F of the '808 Patent discloses control elements 128 and 130 on the resilient fork of the dose counter:

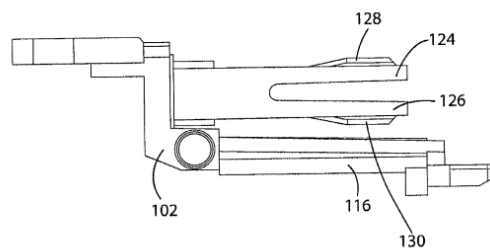
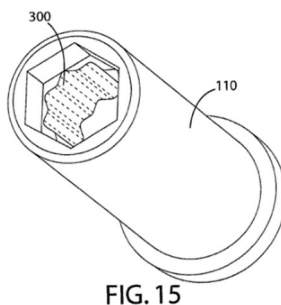


FIG. 6F

'808 Patent, Fig. 6F, 18:8.

770. In addition, Figure 15 of the '808 Patent discloses a tape stock bobbin that comprises “an inwardly facing generally cylindrical engagement surface 300 with a wavelike form extending partially therealong. The engagement surface 300 has a cross-section perpendicular to the longitudinal length of the stock bobbin”:



'808 Patent, Fig. 15, 18:12-17.

771. The '950 Publication discloses no such features or anything that would be expected to function in the same manner. Nothing in the '950 Publication suggests that the interaction between the stock bobbin and the split hub modulates the movement of the counter display to incremental movements, as Asserted Claim 1 of the '808 Patent requires, including, for example, by suggesting that the bobbin has complementary features to match the radial axis nubs in Figure 15. By way of further example, nothing in the '950 Publication suggests that the hexagonal structure of the bobbin continues into the interior of the bobbin or engages with the radial axis nubs. Nor does any disclosure of the '950 Publication discuss any such features. The '552 Publication is largely silent on the features of the radial axis nubs.

772. Mr. Anderson states that the “frictional engagement” created by the radial nubs described in the '950 Publication “modulate the motion of the counter display at the first station to incremental movements.” Anderson Opening Rep. ¶ 448. He also posits the following:

However, in my opinion, the axial nubs are disclosed to provide friction against rotation, even without complementary features. *See* '950 Publication at [0057]. The provided friction, at a minimum

works with the other features of the device (ratchet wheel, clutch spring, actuator pawl) to move the counter display tape forward incrementally, without unwanted winding.

Anderson Opening Rep. ¶ 449.

773. Contrary to Mr. Anderson's suggestion, nothing in the '950 Publication suggests that the radial axial nubs modulate the motion of the counter display to *incremental* movements, as Asserted Claim 1 of the '808 Patent requires. Instead, as the '950 Publication merely states that the radial nubs "creat[e] resilient resistance to rotation of the bobbin 132 on the shaft 142." '950 Publication, [0057]. Nothing in the '950 Publication suggests that the dose counter moves incrementally, much less that the radial axis nubs in this embodiment have any effect in achieving that outcome. To the contrary, the POSA would understand the '950 Publication's emphasis on the radial axis nubs' maintaining tension to mean that it resisted movement generally—not that the device modulated the movement of the counter display to incremental movements.

774. Moreover, contrary to Mr. Anderson's position, nothing in the '950 Publication indicates that the "axial nubs," alone or in combination with other features (e.g., a ratchet wheel, clutch spring, actuator pawl, etc.), regulate the counter display to incremental movements. In sum, nothing in the '950 Publication shows that the radial axis nubs modulate the motion of the counter display to *incremental* movements, as Asserted Claim 1 of the '808 Patent requires. Figure 15 of the '950 Publication, which purports to show the dose counter within the body of the inhaler, clearly shows the absence of a regulator.

775. To be clear, I do not suggest that the only way to achieve a regulator is via the interaction of the nubs on a split hub and the wavelike engagement surface with concavities on the stock bobbin which engage the nubs on the split hub. But Mr. Anderson has failed to identify any additional aspects of this prior art reference that could serve as a regulator.

776. The '808 Patent itself provides additional evidence that the POSA would not have understood the radial axis nubs disclosed in the '950 Publication to regulate the counter display to incremental movements. The '808 Patent acknowledges the prior art's description of a device comprising a mechanism—like the radial nubs described in the '950 Publication—“to hold the stock bobbin taut,” but distinguishes prior art devices on the ground that such mechanisms were inadequate to prevent the dose counter from counting, if for example, such devices were “dropped on a hard surface.” '808 Patent, 2:5-40. The '808 Patent describes that the “regulator is advantageous in that it helps prevent unwanted motion of the counter display if the counter is dropped.” '808 Patent, 2:54-56. Consistent with the '808 Patent's descriptions, the POSA would understand that the '950 Publication not to disclose such a “regulator.”

777. Teva's documents further confirm that the '950 Publication does not disclose a “regulator.” Specifically, before Teva implemented one embodiment of a “regulator” (as set forth in the '808 Patent) in its inhalers, Teva unexpectedly found that continuous or frictional resistance like that provided by radial axis nubs did not modulate the counter display to incremental movements. *See, e.g.*, TEVAQVAR-00737016, at -7016-018; TEVAQVAR-00032306; TEVAQVAR-00032308; *see also* TEVAQVAR-00734380; TEVAQVAR-00734383. Teva noticed that the counter display in its inhalers was moving even without a user actuating the device. *See id.* As that history demonstrates, the resistance like that provided by the radial axis nubs disclosed in the '950 Publication does not necessarily modulate the counter display to incremental movements, as Asserted Claim 1 of the '808 Patent requires, and the POSA would not have understood such a combination to do so.

778. In sum, it is my opinion that the '950 Publication does not anticipate Asserted Claim 1 of the '808 Patent.

* * *

779. I note that the '552 and '950 Publications were before the examiner during prosecution of the '808 Patent. *See, e.g.,* '808 Patent, U.S. Patent Documents, Foreign Patent Documents. I have conducted an independent analysis of the '552 and '950 Publications, and in my opinion, the '552 and '950 Publications do not anticipate the Asserted Claims. The fact that the examiner made the same determinations as to each of these claims (in the case of the '950 Publication, after the Board reversed the examiner's initial determination) provides further evidence that the '552 and '950 Publications do not anticipate those claims.

2. Mr. Anderson's Obviousness Theories Are Incorrect

a. The '552 Publication Does Not Render Obvious the Asserted Claims of the '808 Patent

780. Mr. Anderson opines that the '552 Publication and the POSA's knowledge render obvious Asserted Claims 1, 27, and 28 of the '808 Patent. *See* Anderson Opening Rep. § XVII.B. I disagree. In my opinion, the '552 Publication does not disclose the inventions recited in those claims; and the POSA would not have had a reason to select, modify, and/or combine aspects of the '552 Publication and/or the POSA's knowledge to develop those inventions with a reasonable expectation of success. I incorporate by reference my analysis of the '552 Publication in Section IV.B as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) The POSA Would Not Have Had a Reason to Select the '552 Publication for Modification

781. As an initial matter, in my opinion, the '552 Publication and/or the POSA's knowledge does not render obvious any claim of the '808 Patent because the POSA would not have had a reason to select the '552 Publication as the basis for designing an inhaler and/or dose counter. Mr. Anderson offers no such reason in his report. As I explained in my opinions

regarding objective indicia of non-obviousness and above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined. *See* Lewis Opening Reps. §§ IX.A-B; *supra* *Supra* Sections VI.A.2 and Section V. Mr. Anderson’s selective reliance on the ’552 Publication provides further evidence that his analysis is based on a hindsight-driven effort to reconstruct the inventions recited in the Asserted Claims rather than a genuine effort to understand how the POSA would have understood the prior art.

782. Additionally, even had the POSA selected the ’552 Publication for modification, the POSA would not have arrived at the inventions of the Asserted Claims. The POSA would not have had a reason to modify the ’552 Publication in the manner Mr. Anderson asserts with a reasonable expectation of success, for the reasons I describe below.

2) Claim 1

i. The ’552 Publication Does Not Render Obvious the Regulator Limitation

783. To begin, Mr. Anderson repeats his flawed argument that the ’552 Publication discloses every element of Asserted Claim 1 of the ’808 Patent. I address these flaws at length (*see supra* Section VI.C.1.a) and incorporate that discussion here in full.

784. Mr. Anderson further argues that, “to the extent it does not explicitly disclose a ‘regulator’ the ’552 Publication still renders that limitation obvious.” Anderson Opening Rep.

¶ 435. To support that argument, Mr. Anderson opines that:

[S]everal prior art references, including the ’950 Publication taught that the protrusions, as seen in the ’552 Publication, were known to be used to provide frictional resistance to rotating. *See* ’950 Publication at [0057]. To the extent that this disclosure of protrusions creating frictional resistance does not explicitly disclose a ‘regulator,’ it would have been obvious to a person of skill in the

art to include ridges, or other shapes on the interior of the stock bobbin to further modulate movement by creating additional resistance. In fact, this solution has been done before. For example, the Severent Diskus inhaler (which has been marketed since 1998 and is a well-known inhalation device with which any person of the skill in the art would be familiar), similarly used a bobbin (with teeth) on a spindle. The interior of the spindle included ridged elements for regulating movement of the drive system for advancing the ribbon.

Anderson Opening Rep. ¶ 436.

785. I disagree. First, to the extent that the '552 or '950 Publications disclosed protrusions that provided frictional resistance to rotation, they do not disclose or even suggest how any features would modulate the counter display to incremental movements, as Asserted Claim 1 of the '808 Patent requires.

786. Second, Mr. Anderson does not offer any reason why the POSA would have had a reason to “further modulate movement by creating additional resistance” or reasonably expected to succeed in achieving such a device, and in my opinion, the POSA would not have had a reason to do so and would not have reasonably expected to succeed in doing so. The '552 and '990 Publications provide no suggestion that any such additional resistance would be needed, and in the absence of a strong reason to change a known design, the POSA would have avoided making changes to the dose counter. For example, although Mr. Anderson opines that the POSA would have desired to increase resistance, the POSA would have understood that resistance was a double-edged sword. In particular, the POSA would have known that increasing the dose counter's resistance to movement would also increase the amount of force needed to actuate the dose counter, affecting its usability for patients. During my work at Chiesi and Vectura, we were always mindful of changes that would affect the user experience of our devices. In my opinion, in the absence of some strong reason to change the device's resistance (which the prior art did not provide), the

POSA would not have done so.

787. Teva’s research and development of the claimed inventions confirms that the POSA would not have had a reason to develop such a “regulator” with a reasonable expectation of success. As explained above, before Teva implemented one embodiment of a “regulator” (as set forth in the ’808 Patent) in its inhalers, Teva unexpectedly found that continuous or frictional resistance like that provided by a stock bobbin/split hub combination and/or radial axis nubs like those disclosed in the ’552 Publication or ’950 Publication did not modulate the counter display to incremental movements. *See, e.g.*, TEVAQVAR-00737016, at -7016-018; TEVAQVAR-00032306; TEVAQVAR-00032308; *see also* TEVAQVAR-00734380; TEVAQVAR-00734383. Teva noticed that the counter display in its inhalers moved even without a user actuating the device. *See id.* As a result, Teva implemented a “regulator” similar to the examples depicted in the ’808 Patent. *See, e.g.*, TEVAQVAR-00737016, at -7016-018; TEVAQVAR-00032306; TEVAQVAR-00032308; TEVAQVAR-00734380; TEVAQVAR-00734383. As that history demonstrates, embodiments relying on continuous or frictional resistance like that provided by the radial axis nubs disclosed in the ’950 Publication would not render obvious a regulator that modules a counter display to incremental movements, as Asserted Claim 1 of the ’808 Patent requires.

788. Third, even were the POSA to have a reason to increase the resistance of the dose counter, that would *still* not have given the POSA a reason to develop the claimed regulator with a reasonable expectation of success. To the extent Mr. Anderson implies that “creating additional resistance” is the same thing as modulating movement, he is incorrect. Indeed, the POSA would have understood that adding too much resistance to the regulator would prevent it from modulating the counter display to incremental movements—the exact opposite of what the claim requires.

789. Fourth, Mr. Anderson’s reliance on the Severent Diskus device is misplaced. Mr.

Anderson offers no evidence to support his assertion that the “toothed bobbin” in the Severent Diskus inhaler functions like a regulator. Instead, Mr. Anderson merely includes an isolated photograph of a component in the Severent Diskus inhaler without providing any context whatsoever. Nowhere does he explain what the “toothed bobbin” actually does or how it functions. He also fails to explain what other components of the Severent Diskus inhaler interact with the “toothed bobbin” or how that interaction modulates the movement of a counter display to incremental movements.

790. Mr. Anderson also does not identify any reason why the POSA would have selected components in the Severent Diskus inhaler for combination with elements of the ’552 or ’950 Publications or reasonably expected to succeed in combining them. Nor does he identify any reason why the POSA would have selected the “toothed bobbin” over other components contained in the Severent Diskus inhaler with a reasonable expectation of success. As I explain above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined, *see supra* Section VI.C.2.a.1), and Mr. Anderson’s selective reliance on the “toothed component” as the basis for modification provides further evidence that his analysis is based on hindsight.

3) Claim 27

791. Asserted Claim 27 depends from Asserted Claim 1 and recites: “The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.” In my opinion, at a minimum, the ’552 Publication and/or the POSA’s knowledge do not render obvious the dose counter as claimed in Asserted Claim 1. *See supra* Section VI.C.2.a.2). Thus, the ’552 Publication and/or the POSA’s knowledge

fail to render obvious this claim for at least this reason.

792. Moreover, Mr. Anderson fails to point to a single component of the '552 Publication that discloses an inhaler having a dose counter having a regulator that “provides a resistance force of greater than 0.1 N against the movement of the counter display.”

793. Instead, Mr. Anderson asserts that “[t]o the extent this limitation is not inherently met by the disclosure of the '552 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler.” Anderson Opening Rep. ¶ 438.

794. I note that Mr. Anderson does not offer an opinion on whether the limitation in Asserted Claim 27 is inherently met by the disclosure of the '552 Publication.

795. In addition, Mr. Anderson provides no evidence for his routine optimization theory. The fact that Mr. Anderson has cited no literature suggests that this limitation is more than a matter of routine optimization. It is incorrect for Mr. Anderson to assert that the requisite force was simply to prevent unwinding of the counter display, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler.

4) Claim 28

796. Asserted Claim 28 depends from Asserted Claim 1 and recites: “The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N.” In my opinion, at a minimum, the '552 Publication and/or the POSA's knowledge do not render obvious the dose counter as claimed in Asserted Claims 1 and 27. *See supra* Sections VI.C.2.a.2)-VI.C.2.a.3). Thus, the '552 Publication and/or the POSA's knowledge fail to render obvious this claim for at least this reason.

797. Moreover, Mr. Anderson fails to point to a single component of the '552

Publication that discloses an inhaler having a dose counter having a regulator that provides a resistance force which is “greater than 0.3 N” against the movement of the counter display.

798. Instead, Mr. Anderson asserts that “[t]o the extent this limitation is not inherently met by the disclosure of the ’552 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler.” Anderson Opening Rep. ¶ 439.

799. I note that Mr. Anderson does not offer an opinion on whether the limitation in Asserted Claim 28 is inherently met by the disclosure of the ’552 Publication.

800. In addition, Mr. Anderson provides no evidence for his routine optimization theory. The fact that Mr. Anderson has cited no literature suggests that this limitation is more than a matter of routine optimization. It is incorrect for Mr. Anderson to assert that the requisite force was simply to prevent unwinding of the counter display, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler.

b. The ’950 Publication Does Not Render Obvious the Asserted Claims of the ’808 Patent

801. Mr. Anderson opines that the ’950 Publication and the POSA’s knowledge render obvious Asserted Claims 1, 27, and 28 of the ’808 Patent. *See* Anderson Opening Rep. § XVII.B. I disagree. In my opinion, the ’950 Publication does not disclose the inventions recited in those claims; and the POSA would not have had a reason to select, modify, and/or combine aspects of the ’950 Publication and/or the POSA’s knowledge to develop those inventions with a reasonable expectation of success. I incorporate by reference my analysis of the ’950 Publication in Section IV.F as though fully set herein. I have not reproduced that section here solely for the sake of brevity.

1) The POSA Would Not Have Had a Reason to Select the '950 Publication for Modification

802. As an initial matter, in my opinion, the '950 Publication and/or the POSA's knowledge does not render obvious any Asserted Claim of the '808 Patent because the POSA would not have had a reason to select the '950 Publication as the basis for designing an inhaler and/or dose counter. Mr. Anderson offers no such reason in his report. As I explained in my opinions regarding objective indicia of non-obviousness and above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined. *See* Lewis Opening Reps. §§ IX.A-B; *supra* Sections VI.A.2 and Section V. Mr. Anderson's selective reliance on the '950 Publication provides further evidence that his analysis is based on a hindsight-driven effort to reconstruct the inventions recited in the Asserted Claims rather than a genuine effort to understand how the POSA would have understood the prior art.

803. Additionally, even had the POSA selected the '950 Publication for modification, the POSA would not have arrived at the inventions of the Asserted Claims. The POSA would not have had a reason to modify the '950 Publication in the manner Mr. Anderson asserts with a reasonable expectation of success, for the reasons I describe below.

2) Claim 1

i. The '950 Publication Does Not Render Obvious the Regulator Limitation

804. To begin, Mr. Anderson repeats his flawed argument that the '950 Publication discloses every element of Asserted Claim 1 of the '808 Patent. I address these flaws at length (*see supra* Section VI.C.1.b) and incorporate that discussion here in full.

805. Mr. Anderson further argues that, "to the extent it does not explicitly disclose a

‘regulator’ the ’950 Publication still renders that limitation obvious.” Anderson Opening Rep.

¶ 451. To support that argument, Mr. Anderson opines that:

[S]everal prior art references, including the ’950 Publication taught that the protrusions, or radially extending nubs, were known to be used to provide frictional resistance to rotating. *See* ’950 Publication at [0057]. To the extent that this disclosure of protrusions creating frictional resistance does not explicitly disclose a ‘regulator,’ it would have been obvious to a person of skill in the art to include ridges, or other shapes on the interior of the stock bobbin to further modulate movement by creating additional resistance. In fact, this solution has been done before. For example, the Severent Diskus inhaler (which has been marketed since 1998 and is a well-known inhalation device with which any person of the skill in the art would be familiar), similarly used a bobbin (with teeth) on a spindle. The interior of the spindle included ridged elements for regulating movement of the drive system for advancing the ribbon.

Anderson Opening Rep. ¶ 453.

806. I disagree. First, to the extent that the ’950 Publication disclosed protrusions that provided frictional resistance to rotation, it did not disclose or even suggest how any features would modulate the counter display to incremental movements, as Asserted Claim 1 of the ’808 Patent requires.

807. Second, Mr. Anderson does not offer any reason why the POSA would have had a reason to “further modulate movement by creating additional resistance” or reasonably expected to succeed in achieving such a device, and in my opinion, the POSA would not have had a reason to do so and would not have reasonably expected to succeed in doing so. The ’950 Publication provides no suggestion that any such additional resistance would be needed, and in the absence of a strong reason to change a known design, the POSA would have avoided making changes to the dose counter. For example, although Mr. Anderson opines that the POSA would have desired to increase resistance, the POSA would have understood that resistance was a double-edge sword. In

particular, the POSA would have known that increasing the dose counter's resistance to movement would also increase the amount of force needed to actuate the dose counter, affecting its usability for patients. In the absence of some strong reason to change the device's resistance (which the prior art did not provide), the POSA would not have done so.

808. Teva's research and development of the claimed inventions confirms that the POSA would not have had a reason to develop such a "regulator" with a reasonable expectation of success. As explained above, before Teva implemented one embodiment of a "regulator" (as set forth in the '808 Patent) in its inhalers, Teva unexpectedly found that continuous or frictional resistance like that provided by the radial axis nubs disclosed in the '950 Publication did not modulate the counter display to incremental movements. *See, e.g.*, TEVAQVAR-00737016, at -7016-018; TEVAQVAR-00032306; TEVAQVAR-00032308; *see also* TEVAQVAR-00734380; TEVAQVAR-00734383. Teva noticed that the counter display in its inhalers moved even without a user actuating the device. *See id.* As a result, Teva implemented a "regulator" similar to the examples depicted in the '808 Patent. *See, e.g.*, TEVAQVAR-00737016, at -7016-018; TEVAQVAR-00032306; TEVAQVAR-00032308; TEVAQVAR-00734380; TEVAQVAR-00734383. As that history demonstrates, embodiments relying on continuous or frictional resistance like that provided by the radial axis nubs disclosed in the '950 Publication would not render obvious a regulator that modulates a counter to display to incremental movements, as Asserted Claim 1 of the '808 Patent requires.

809. Third, even were the POSA to have a reason to increase the resistance of the dose counter, that would *still* not have given the POSA a reason to develop the claimed regulator with a reasonable expectation of success. To the extent Mr. Anderson implies that "creating additional resistance" is the same thing as modulating movement, he is incorrect. Indeed, the POSA would

have understood that adding too much resistance to the regulator would prevent it from modulating the counter display to incremental movements—the exact opposite of what the claim requires.

810. Fourth, Mr. Anderson’s reliance on the Severent Diskus device is misplaced. Mr. Anderson offers no evidence to support his assertion that the “toothed bobbin” in the Severent Diskus inhaler functions like a regulator. Instead, Mr. Anderson merely includes an isolated photograph of a component in the Severent Diskus inhaler without providing any context whatsoever. Nowhere does he explain what the “toothed bobbin” actually does or how it functions. He also fails to explain what other components of the Severent Diskus inhaler interact with the “toothed bobbin” or how that interaction modulates the movement of a counter display to incremental movements.

811. Mr. Anderson also does not identify any reason why the POSA would have selected components in the Severent Diskus inhaler for combination with elements of the ’950 Publication or reasonably expected to succeed in combining them. Nor does he identify any reason why the POSA would have selected the “toothed bobbin” over other components contained in the Severent Diskus inhaler with a reasonable expectation of success. As I explain above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined, *see supra* VI.C.2.b.1), and Mr. Anderson’s selective reliance on the “toothed component” as the basis for modification provides further evidence that his analysis is based on hindsight.

3) Claim 27

812. Asserted Claim 27 depends from Asserted Claim 1 and recites: “The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.” In my opinion, at a minimum, the ’950 Publication

and/or the POSA's knowledge do not render obvious the dose counter as claimed in Asserted Claim 1. *See supra* Section VI.C.2.b.2). Thus, the '552 Publication and/or the POSA's knowledge fail to render obvious this claim for at least this reason.

813. Moreover, Mr. Anderson fails to point to a single component of the '950 Publication that discloses an inhaler having a dose counter having a regulator that "provides a resistance force of greater than 0.1 N against the movement of the counter display."

814. Instead, Mr. Anderson asserts that "[t]o the extent this limitation is not inherently met by the disclosure of the '950 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler." Anderson Opening Rep. ¶ 455.

815. I note that Mr. Anderson does not offer an opinion on whether the limitation in Asserted Claim 27 is inherently met by the disclosure of the '950 Publication.

816. In addition, Mr. Anderson provides no evidence for his routine optimization theory. The fact that Mr. Anderson has cited no literature suggests that this limitation is more than a matter of routine optimization. It is incorrect for Mr. Anderson to assert that the requisite force was simply to prevent unwinding of the counter display, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler.

4) Claim 28

817. Asserted Claim 28 depends from Asserted Claim 27 and recites: "The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N." In my opinion, at a minimum, the '950 Publication and/or the POSA's knowledge do not render obvious the dose counter as claimed in Asserted Claims 1 and 27. *See supra* Sections VI.C.2.a.2)-VI.C.2.a.3). Thus, the '950 Publication and/or the POSA's knowledge fail to render obvious this claim for at least

this reason.

818. Moreover, Mr. Anderson fails to point to a single component of the '950 Publication that discloses an inhaler having a dose counter having a regulator that provides a resistance force which is "greater than 0.3 N" against the movement of the counter display.

819. Instead, Mr. Anderson asserts that "[t]o the extent this limitation is not inherently met by the disclosure of the '950 Publication, it would be a matter of routine optimization for a POSA to arrive at the requisite force against movement of the counter display to prevent unwinding, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler." Anderson Opening Rep. ¶ 456.

820. I note that Mr. Anderson does not offer an opinion on whether the limitation in Asserted Claim 28 is inherently met by the disclosure of the '950 Publication.

821. In addition, Mr. Anderson has provided no evidence for his routine optimization theory. The fact that Mr. Anderson has cited no literature suggests that this limitation is more than a matter of routine optimization. It is incorrect for Mr. Anderson to assert that the requisite force was simply to prevent unwinding of the counter display, while also allowing the drive system to incrementally move the counter display forward upon actuation of the inhaler.

c. The '406 Publication Does Not Render Obvious the Asserted Claims of the '808 Patent

822. Mr. Anderson opines that the '406 Publication renders obvious Asserted Claims 1, 27, and 28 of the '808 Patent. For each claim and limitation he analyzes, Mr. Anderson repeats the assertion that if Defendants infringe the '808 Patent, then the '406 Patent necessarily renders obvious the '808 Patent because "Defendants' ANDA Products practice the invention disclosed in the '406 Publication." See Anderson Opening Rep. § XVII.E. I disagree. I incorporate by reference my analysis of the '406 Publication in Section IV.A as though fully set herein. I have

not reproduced that section here solely for the sake of brevity.

1) The POSA Would Not Have Had a Reason to Select the '406 Publication for Modification

823. As an initial matter, in my opinion, the '406 Publication does not render obvious any Asserted Claim of the '808 Patent because the POSA would not have had a reason to select the '406 Publication as the basis for designing an inhaler and/or dose counter. Mr. Anderson offers no such reason in his report. As I explain in my opinions regarding objective indicia of non-obviousness and above, the prior art disclosed numerous inhalers and dose-counting mechanisms that did not practice the inventions recited in the Asserted Claims and did not offer any specific guidance or direction as to which of those inhalers and/or dose-counting mechanisms should be selected, modified, and/or combined. *See* Lewis Opening Rep. §§ IX.A-B; *supra* Section VI.

824. Additionally, as I explain above in responding to Mr. Anderson's opinions relating to the '289 and '587 Patents, the '406 Publication describes five distinct dose counters that can be used in an inhaler. One dose counter is described in Paragraphs [0090]-[00116] in conjunction with Figures 1-11. A second dose counter is described in Paragraphs [00117]-[00134] in conjunction with Figures 12-20. A third dose counter is described in paragraphs [00135]-[00159] in conjunction with Figures 21-30. A fourth dose counter is described in paragraphs [00160]-[00170] in conjunction with Figures 31-40. A fifth dose counter is described in paragraphs [00171]-[00182] in conjunction with Figures 41-47. *See supra* Section VI.A.1.a.1)a).

825. Mr. Anderson's opinions that the '406 Publication renders obvious the Asserted Claims of the '808 Patent mix and match various disclosures from these five separate examples indiscriminately, without identifying any reason why the POSA would have done so. I do not agree with this approach, because the '406 Publication describes these embodiments as different dose counters, and the POSA would not understand a feature of one to be interchangeable with a

feature of another. If anything, the disclosure of five distinct dose counters, none of which individually embodies the claimed inventions, reinforces the validity of the Asserted Claims.

2) Claim 1

826. Additionally, in my opinion, the '406 Publication does not render obvious Asserted Claim 1 of the '808 Patent (and, therefore, does not render obvious any Asserted Claim) because it does not render obvious limitations in Asserted Claim 1.

827. Among other things, Asserted Claim 1 of the '808 Patent recites: “wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.”

828. In my opinion, the '406 Publication does not provide any information that would have given the POSA a reason to develop an inhaler and dose counter that satisfied those limitations with a reasonable expectation of success. To the contrary, based on the '406 Publication's two-dimensional disclosures, the POSA would not understand the '406 Publication to disclose and/or render obvious this limitation and, therefore, would not understand to anticipate and/or render obvious any of the other claims. For example, the '406 Publication does not disclose that the purpose of the leaf spring is to regulate the counter display to incremental movements. Nothing in the '406 Publication discloses that the leaf spring prevents the dose counter from counting, if for example, an inhaler device was dropped on a hard surface. Nor can that purpose be deduced from the '406 Publication's descriptions and figures.

3) Claim 27

829. Asserted Claim 27 of the '808 Patent depends from Asserted Claim 1 and recites: “The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.” In my opinion, at a minimum, the '406 Publication and/or the POSA's knowledge do not render obvious the “dose counter as claimed

in claim 1.” *See supra* Section VI.C.2.c.2). Additionally, in my opinion, the ’406 Publication and/or the POSA’s knowledge do not render obvious a dose counter “in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.” The ’406 Publication provides no such measurements, nor can they be informed. The POSA also would not have had a reason to develop such a dose counter with a reasonable expectation of success based on the ’406 Publication alone or in combination with the POSA’s knowledge. Thus, the ’406 Publication and the POSA’s knowledge fail to render obvious this claim.

4) Claim 28

830. Asserted Claim 28 of the ’808 Patent depends from Asserted Claim 27 and recites: “The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N.” In my opinion, at a minimum, the ’406 Publication and/or the POSA’s knowledge do not render obvious the “dose counter as claimed in claim 27.” *See supra* Sections VI.C.2.c.2)-VI.C.2.c.3). Additionally, in my opinion, the ’406 Publication and/or the POSA’s knowledge do not render obvious a dose counter “in which the regulator provides a resistance force “greater than 0.3 N” against movement of the counter display. The ’406 Publication provides no such measurements, nor can they be informed. The POSA also would not have had a reason to develop such a dose counter with a reasonable expectation of success based on the ’406 Publication alone or in combination with the POSA’s knowledge. Thus, the ’406 Publication and the POSA’s knowledge fail to render obvious this claim.

* * *

831. In sum, I disagree with Mr. Anderson’s conclusions that the Asserted Claims would have been obvious, including based on the references and supposed knowledge that he describes in his reports. However, even if Mr. Anderson could show that the Asserted Claims would have been obvious in view of those arguments, in my opinion, strong objective indicia of non-

obviousness establish that the claims are not invalid. *See* Lewis Opening Reps. § IX.

832. I further note that the '552 and '950 Publications were before the examiner during prosecution of the '808 Patent. *See, e.g.,* '808 Patent, U.S. Patent Documents, Foreign Patent Documents. I have conducted an independent analysis of the '552 and '950 Publications, and in my opinion, the '552 and '950 Publications do not render obvious the Asserted Claims, alone or in combination with the purported knowledge that Mr. Anderson describes. The fact that the examiner made similar determinations as to each of these claims (in the case of the '950 Publication, after reversal by the Board) provides further evidence that the '552 and '950 Publications do not render obvious those claims.

3. The Asserted Claims Are Adequately Described and Enabled

833. Mr. Anderson opines that Asserted Claims 1, 27, and 28 of the '808 Patents are invalid for lack of written description and are invalid for lack of enablement under Teva's proposed construction of the term "counter display arranged to indicate dosage information." I disagree with Mr. Anderson. In my opinion, the POSA would understand the '808 Patent to convey that the inventors possessed the full scope of the subject matter recited in Asserted Claims 1, 27, and 28. Additionally, in my opinion, the POSA be able, in view of the '808 Patent, its prosecution histories, and his or her knowledge, to make and use the full scope of the inventions without undue experimentation.

834. Mr. Anderson appears to premise his written description and enablement opinions based on a purported distinction between (1) devices that comprise a single counter display consisting of a single component; and (2) devices that comprise multiple counter displays or counter displays consisting of multiple components.

835. With respect to written description, Mr. Anderson states that under Plaintiffs' construction of "counter display arranged to indicate dose information," a display may "be

comprised of multiple displays or components, which may move independently of each other.”

Anderson Opening Rep. ¶ 465. Mr. Anderson then states:

Under Plaintiffs’ proposed construction, the claim would encompass devices including a device having two separate displays. For example, such a device could include two separate tapes, one displaying tens and one displaying units In order to display remaining doses, each of these tapes would need to move independently of each other. For example, the tape displaying the tens would move only every ten ejections, while the tape displaying units would move with every ejection.

Anderson Opening Rep. ¶ 466.

836. Mr. Anderson states that because the ’808 Patent does not include a “disclosure of multiple displays” or does not “disclos[e] or teach[] of mechanisms for independently moving separate displays,” the “Asserted Claims of the ’808 Patent are invalid for lack of written description support.” Anderson Opening Rep. ¶ 467.

837. Similarly, with respect to enablement, Mr. Anderson states:

In addition, in my opinion, a POSA would be left to determine how to move the units display every ejection, while moving the tens display only once every ten ejections and how to fit mechanisms for such movement in a very small space, all with zero guidance from the specification. Given the breadth of Plaintiffs’ construction, the nature of inhalers (very small space to insert counter mechanisms), the lack of any direction provided by the specification, the lack of working examples with the type of multi-part counter display dose counter that Plaintiffs’ construction encompasses, and the likely extensive experimentation a POSA would need to engage in to develop a multi-part counter display dose counter, under Plaintiffs’ construction, the Asserted Claims of the ’808 Patent are also invalid for lack of enablement.

Anderson Opening Rep. ¶ 468

838. I disagree with Mr. Anderson’s position. As an initial matter, Mr. Anderson’s distinction between devices comprising a single counter display consisting of a single component and devices comprising multiple counter displays or counter displays consisting of multiple

components does not accurately reflect how the POSA would have viewed the technology at issue. The prior art recognized no distinction between counter displays comprised of a single component or multiple components or devices containing a single counter display or multiple counter displays. To the contrary, such mechanisms for displaying information was well known, *see, e.g.*, Lewis Opening Rep. §§ IX.A-B; *supra* Section V, and the POSA would have understood that the '808 Patent's descriptions of counter displays, *see, e.g.*, '808 Patent, Abstract, 2:44-53, 8:31-50, encompassed those mechanisms. Mr. Anderson's reliance on this distinction in an apparent effort to undermine the validity of the Asserted Claims provides further evidence that his analysis is driven by hindsight.

839. Additionally, the POSA would have understood the '808 Patent's descriptions to describe and enable the embodiments that Mr. Anderson opines that it does not. The '808 Patent's specification refers to devices comprising a "counter display," *see, e.g.*, '808 Patent, Abstract, 2:44-53, 8:31-50, which the POSA would understand to describe devices comprising multiple counter displays or counter displays consisting of multiple components. As I explain in the paragraph above, at the time of the inventions, multi-component displays were well known, and the POSA would understand the '808 Patent's disclosures to encompass such devices. Contrary to Mr. Anderson's contention, the POSA would not understand that the '808 Patent failed to adequately describe or enable multi-display or multi-component counter displays just because the numbered Figures and accompanying descriptions in the '808 Patent do not expressly depict one.

840. To the extent that the POSA would need to conduct any experiments to implement a device comprising multiple counter displays or a counter display consisting of multiple components, the POSA could do so without resorting to undue experimentation in view of the '808 Patent and his or her knowledge of the art. The '808 Patent's specification describes the use of

counter displays to display dosage information. *See, e.g.*, '808 Patent, Abstract, 2:44-53, 8:31-50. And the POSA would know, based both on the '808 Patent and her background knowledge, that devices could be implemented multiple displays or counter displays consisting of multiple components. *See, e.g.*, Lewis Opening Rep. §§ IX.A-B; *supra* Section V. To the extent the '808 Patent's specification does not identically set forth every embodiment within the scope of the claims, the POSA would have been able to bridge the gaps between the precise disclosures and the full scope of the claims without undue experimentation.

841. I note that Mr. Anderson describes only a single example of a counter display that the '808 Patent specification supposedly does not describe or enable—namely, a device comprising a counter display consisting of multiple display tapes, one of which displayed the tens digit and another of which displayed the ones digit. *See* Anderson Opening Rep. ¶¶ 466, 468. In my opinion, were the POSA inclined to desire such a device (a possibility for which Mr. Anderson provides no evidence), the POSA, with the benefit of the '808 Patent, could do so by adding a second tape to a single-tape device (which Mr. Anderson admits that the '808 Patent discloses) and modifying the shafts or other structures around which the tapes were wound so that every ten actuations of the ones tape caused the tens tape to actuate. Indeed, Mr. Anderson himself cites multiple prior art references disclosing similar mechanisms. *See, e.g.*, Anderson Opening Rep. ¶¶ 52-54 (citing, e.g., '406 Publication; '008 Publication; '021 Publication, '518 Publication); *see also* '008 Publication ¶¶ [0048], [0053], Figs. 4a-4d; '021 Publication, ¶¶ [0097]-[0103], Figs. 25, 28-48, '518 Publication [0011], [0088]-[0107], [0143]-[167], Figs. 8-13, 25-27d). And even assuming, contrary to my opinion, that the '808 Patent specification did not describe or enable Mr. Anderson's example, that example is insignificant compared to the full scope of the Asserted Claims.

VII. Conclusion

842. For the reasons stated above, I disagree with Mr. Anderson's opinions that the '289 and '587 Patents are invalid. It is my opinion that each of the Asserted Claims is valid in view of the prior art set forth by Mr. Anderson, that Asserted Claim 12 of the '156 Patent is not indefinite, and that Asserted Claims 1, 27, and 28 of the '808 Patents are adequately described and enabled.

Dated: June 14, 2022

A handwritten signature in black ink, consisting of a stylized 'D' followed by a 'L' and a 'W', with a horizontal line extending from the end of the 'W'.

Dr. David Lewis, PhD..

Exhibit B – Exemplary Images of Inhaler Products that Do Not Contain Support Rails

Budair®



For a description of the Chiesi Jet with spacer as utilized in Budair® that shows the absence of support rails as of the priority date, please see WO 01/49350.

Atrovent®

Figure 1, Atrovent Inhaler, CFC Free 20µg per dose MDI (ipratropium bromide, Boehringer Ingelheim) MDI does not have support ribs in the transparent housing.



Figure 2, Atrovent Inhaler, CFC Free 20 μ g per dose MDI (ipratropium bromide, Boehringer Ingelheim) MDI does not have support ribs in the transparent housing.



Figure 3, Atrovent Inhaler, CFC Free 20µg per dose MDI (ipratropium bromide, Boehringer Ingelheim) MDI does not have support ribs in the transparent housing.

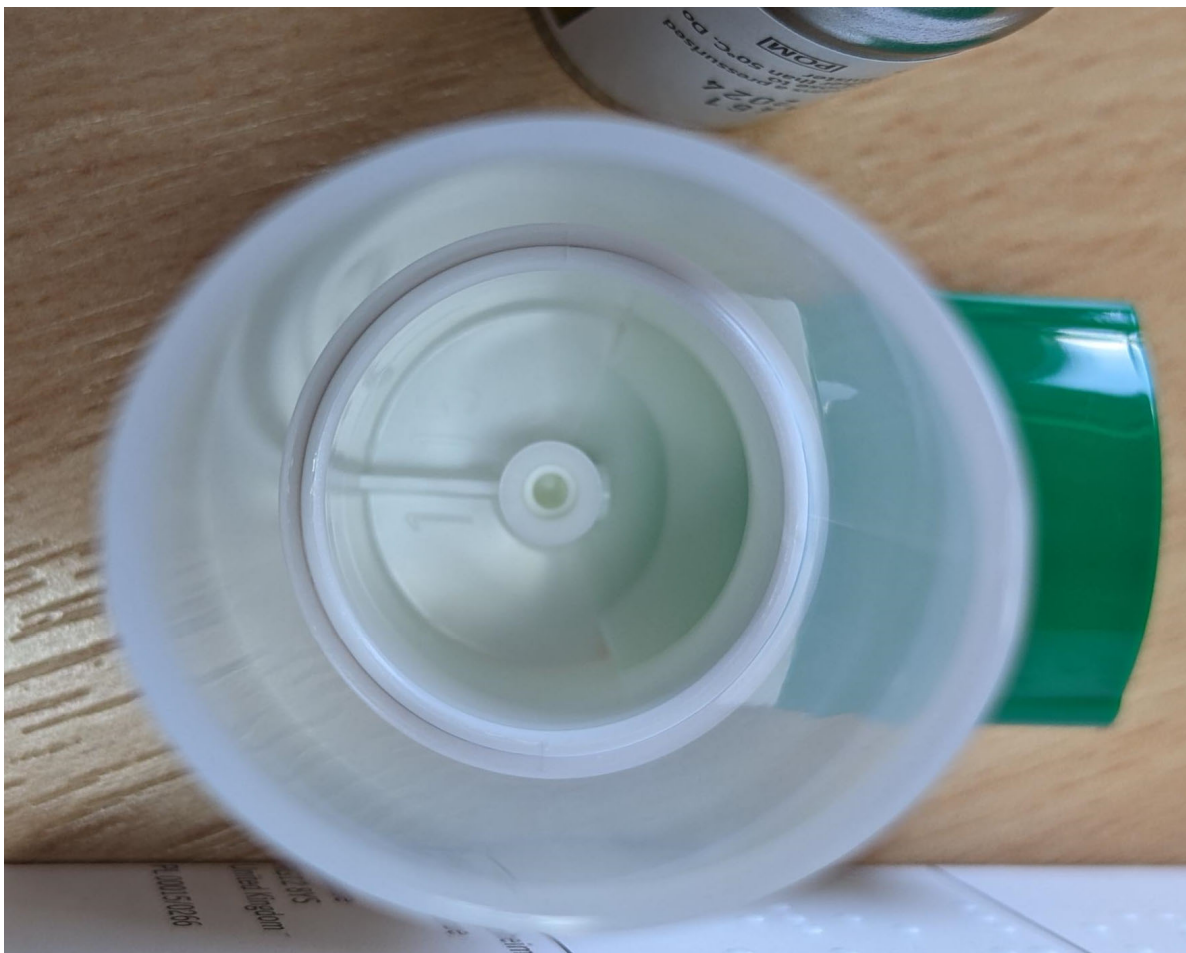


Figure 4, Atrovent Inhaler, CFC Free 20µg per dose MDI (ipratropium bromide, Boehringer Ingelheim) MDI does not have support ribs in the transparent housing.

Atrovent was marketed before the priority date and it did not contain support rails as of that date. See, e.g., https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021527s000_PRNTLBL.pdf

Alupent®



Figure 5, Alupent MDI (metaproterenol sulfate, Boehringer Ingelheim) MDI does not have support ribs in the transparent housing.

Alupent was marketed before the priority date and it did not contain support rails as of that date. *See, e.g.,* <https://www.proquest.com/docview/229950790?pq-origsite=gscholar&fromopenview=true>.

Berodual®



Figure 6, Berodual MDI (ipratropium bromide, fenoterol hydrobromide, Boehringer Ingelheim) MDI does not have support ribs in the transparent housing.

Berodual was marketed before the priority date and it did not contain support rails as of that date. *See, e.g.,* [https://www.jacionline.org/article/S0091-6749\(99\)70042-4/pdf](https://www.jacionline.org/article/S0091-6749(99)70042-4/pdf).

Berotec®



Figure 7, Berotec MDI (fenoterol hydrobromide, Boehringer Ingelheim) does not have support ribs in the transparent housing.

Berotec was marketed before the priority date and it did not contain support rails as of that date. *See, e.g.,* <https://www.sciencedirect.com/science/article/pii/S0954611100908643>.

Combivent®

Figure 8, Combivent MDI (ipratropium bromide and albuterol sulfate, Boehringer Ingelheim) does not have support ribs in the transparent housing.

Combivent was marketed before the priority date and it did not contain support rails as of that date. *See, e.g.,* <https://web.archive.org/web/20070625172405/http://www.combivent.com/combiventwebsite/video.html> (also accessible via <https://web.archive.org/web/20070625163430/http://www.combivent.com/combiventwebsite/index.html> and clicking on the link “View Patient Video.”)

Exhibit A

David Andrew Lewis BSc MSc PhD

Address: 10 Southerwicks, Corsham, Wiltshire, SN13 9NH, UK

Date of Birth: 6 June 1968

Education:

BSc (Hons) 1989, Physics, University of Essex

MSc 1991, Chemistry, University of Essex, by dissertation: "Spray Characteristics of pressurized packages containing chlorofluorocarbon and hydrocarbon propellant formulations".

PhD 1994, Chemistry, University of Essex, Thesis title: "The evaporation and diffusion of nicotine from mainstream tobacco smoke".

Employment:

17 July 2015 – Present: Director of Oz-UK Limited

Development of inhaled pharmaceutical products. Bespoke research relating to formulation, packaging and design of metered dose inhalers, dry powder inhalers and nebulisers.

7 April 2008 – Present Director of 3DI Solutions Limited

Consultancy for inhaled pharmaceutical products and in-vitro data processing.

01 Aug 2008 – 31 Aug 2020: Director of Aerosol Science, Chiesi Limited, UK (2017-2020)

Head of Laboratory, Chiesi Limited, UK (2008 – 2017)

David joined Chiesi Limited in 2008 and founded the UK Research Centre in Chippenham, UK (Official opening: 9 July 2009). The site was established as the centre of excellence for Chiesi's dry powder inhaler and metered dose inhaler products. During the period 2009-2013 David published 135+ research papers.

In 2014 David founded the bi-annual Research Meeting (Innovation in Inhalation); a one-two day multidisciplinary event with invited internationally recognised speakers. The meeting took place in the UK during 2014, 2016 and 2018 and in Italy during 2019.

In addition, to supervising up to fifteen full-time scientists, David was industrial supervisor for ten PhD students and two post-doc research fellows in collaborations with Bath University, Bristol University, Alberta University, Loughborough University, Sydney University, Monash University, Kings College London, University of Hertfordshire and National Centre for Scientific Research "Demokritos."

07 May 1996 – 01 May 2008: Head of HFA Programmes, Vectura Limited, UK

David joined the Centre for Drug Formulation Studies at Bath University, England, in May 1996 to lead a start-up HFA programme sponsored by Chiesi Farmaceutici. The resultant successful development of HFA solution formulations led to a rapid expansion of his group which transferred to Vectura in 1999 as a result of CDFS spin-out by the University of Bath. During this period, he authored extensive research publications within the fields of pharmaceuticals, analytical chemistry, and aerosol science, and was co-inventor of >30 patents relating to pressurized metered dose inhaler formulations and devices. These inventions led to the Chiesi Modulite technology which has seen formulations of beclomethasone dipropionate, budesonide, formoterol and a beclomethasone dipropionate-formoterol combination becoming commercialized in several European countries.

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131. Brambilla G; Ganderton D; Lewis D A; Church T K; Meakin B J and Howlett D (1999). 'Through Can Life Variation in Delivered Dose from pMDIs'. 136th British Pharmaceutical Conference and Pharmex, Cardiff.
132. Brambilla G; Ganderton D; Lewis D A; Meakin B J and Garzia R (1999). 'The Modulation of Clouds Generated by pMDIs. J. Aerosol med. (12) 119.
133. Meakin B J; Lewis D A; Ganderton D et al. (1998). 'effects of actuator orifice diameter on Beclomethasone Dipropionate Delivery from a pMDI HFA Solution Formulation'. Proc. Respiratory Drug Delivery VI, Buffalo Grove, Interpharm Press, pp. 363 - 366.

Other Refereed Publications:

133. D. Lewis "Extrafine particles and the potential for enhanced inhaled drug delivery" (2016), OINCP, Jan 2017.
134. D. Lewis, A Tweedie (2016), "Enhancing the Performance of Dry Powder Inhalers: Breath Actuated Mechanisms", On Drug Delivery, No 66, 34-38.
135. D. Lewis (2015), "Expert Opinion: Reviewing Current Thinking on the In Vivo Behavior of Particles in the Extra-Fine Region", 1 Dec 2015, 4 - 9.

2012 – 2021: David is Chief Investigator for >AUD\$1.2M Australian Research Council funded projects including:

- 2010-2013 ARC-Linkage funding AUS\$464,400; Sydney University LP100200156 Dr D Traini; A/Prof PM Young; Prof HK Chan: "Engineering Pressurized Liquid Droplets to Generate High Efficiency Aerosols for Targeted Respiratory Delivery".
- 2012-2015 ARC-Linkage funding \$340,000; Sydney University (ARC LP120200744) Prof D Traini; Prof PM Young; Prof D Fletcher: "Ultra-low dose dry powder inhaler technology for the treatment of respiratory diseases".
- 2017-2020 ARC-Linkage Funding AUS\$330k Monash University (ARC LP160101845) Prof PM Young; Prof D Honnery; Dr Edgington-Mitchell; Dr David Lewis, "Improving respiratory drug delivery through targeted nozzle design".
- 2018-2021 ARC-Linkage Funding AUS\$555k Monash University (ARC LP170100551) Prof Daniela Traini, Prof Julio Soria, Adj/Prof David Fletcher, "Smart hybrid system for the

formulation and design of dry powder inhalers”.

Industrial Supervisor (Post-Doctoral Researchers):

2018 - 2020: Industrial Postdoc Researcher “Particle Engineering for Pulmonary Drug Delivery”

- Dr George Kylafis, National Centre for Scientific Research “Demokritos”, Athens, Greece: funded Post-Doctoral project with Niarchos Foundation.

2016 - 2020: Postdoc Researcher “Inhalation Aerosol and Response to Humidity”

- Dr Allen Haddrell, Research Fellow, School of Chemistry, Bristol University.

Industrial Supervisor (PhD Studentships):

2010 – 2014: Farzin Molaghasem Shemirani, (PhD) “Metered Dose Inhaler Aerosols: Efficiency, Particle Engineering and Atomization”, Department of Mechanical Engineering, University of Alberta.

Deliverables:

- M Azhdarzadeh, F Shemirani, C Ruzycki, A Baldelli, J Ivey, D Barona, T Church, D Lewis, J Olfert, W Finlay, R Vehring. (2016). 'An atomizer to generate monodisperse droplets from high vapor pressure liquids'. J Atom & Sprays, 26 (2) 121-134.
- Shemirani, F. M., Church, T. K., Lewis, D. A., Finlay, W. H., Vehring, R. (2015) Onset of Flash Atomization in a Propellant Micro-jet. Journal of Fluids Engineering, 137, 091101-1 – 0911019.
- Shemirani F.M., Hoe, S., Lewis, D., Church, T., Vehring, R., Finlay, WH. (2013) 'Effect of ambient temperature and humidity on the in vitro regional lung deposition of solution and suspension MDIs' J. Aerosol Med. & Pulm. Drug Del. Vol 26 (2) A35.
- Shemirani F. M.; Hoe S.; Lewis D.; Church T.; Vehring R.; Finlay W. H.; (2012) 'In Vitro Investigation of the Effect of Ambient Humidity on Regional Delivered Dose with Solution and Suspension MDIs' J. Aerosol Med. & Pulm. Drug Del. 26 (0) 1-8
- Shemirani F. M. Mohammad T. Fong J. Azhdarzadeh M. Church T. K. Lewis D. A. Finlay W. H. Vehring R. 'A Continuous, Monodisperse Propellant Microdroplet Stream as a Model System for Laser Analysis of Mass Transfer in MDI Sprays'. RDD 2012 773-776.

2012 – 2015: Yang Chen, (PhD) “The Influence of device and formulation parameters on aerosol electrostatics for pressurised metered dose inhalers”, Sydney Medical School, University of Sydney.

Deliverables:

- Chen Y, Young PM, Murphy S, Fletcher DF, Long E, Lewis D, Church T, Traini D (2016) 'High-Speed Laser Image Analysis of Plume Angles for Pressurized Metered Dose Inhalers: The Effect of Nozzle Geometry' AAPS PharmSciTech. 17 June 2016.
- Chen Y., Young P.M., Fletcher D., Chan H. K., Long E., Lewis D., Church T., Traini D., (2015) 'The Effect of Active Pharmaceutical Ingredients on Aerosol Electrostatic Charges from Pressurized Metered Dose Inhalers'. J Pharm Res. 32 (9) 2928-36.
- Chen Y., Young P.M., Fletcher D., Chan H. K., Long E., Lewis D., Church T., Traini D., (2014) 'The influence of actuator materials and nozzle designs on electrostatic charge of pressurised metered dose inhaler (pMDI) formulations.' Pharm Res, 31, 1325-1337.
- Chen., Y., Traini, D., Fletcher, D., F., Chan, H., K., Lewis, D., A., Church, T., K., Young, P., M., (2014). 'The Effect of Active Pharmaceutical Ingredients on Aerosols Electrostatic Charges for Pressurised Metered Dose Inhalers', RDD (3) 707-710.
- Chen, Y., Traini, D., Fletcher D., Chan, H. K., Lewis, D., Church, T., Young P. M., (2013) 'Investigation of nozzle designs and material on the electrostatic charge of pressurised metered dose inhaler ' Drug Delivery to the Lungs 11-13th Dec 2013.
- Chen, Y., Traini, D., Fletcher D., Chan, H. K., Lewis, D., Church, T., Young P. M., (2013) 'The effect of pressurised metered dose inhaler (pMDI) actuator orifice geometries on aerosols

triboelectrification' Respiratory Drug Delivery 2013 Vol 2, 439-444.

- Chen, Y., Traini, D., Chan, H. K., Lewis, D., Church, T., Young P. M., (2012) 'Investigation of the electrostatic charging effect of different actuator materials and design on pMDI aerosols' Drug Delivery to the Lungs 2012. 5-7th Dec 2012, pp 212 - 215.
- Chen Y. Wong W. H. W. Lewis D. Church T. Traini D. Young P. M. (2012) 'Triboelectrification study of a pressurised metered dose inhaler (pMDI) formulation using different actuator materials and orifice designs' Proc. RDD 2012, pp 845 - 850.

2012 – 2015: Barzin Gavtash, “CFD Simulation of Pressurized Metered Dose Inhaler”, Wolfson School of Mechanical and Manufacturing Engineering, Loughborough University.

Deliverables:

- Versteeg H, Hargrave GK, Myatt BJ, Lewis D, Church T, Brambilla G, (2017) Using Phase Doppler Anemometry & High Speed Imaging to Analyze MDI Spray Plume Dynamics (accepted for publication), RDD Europe, Nice.
- B. Gavtash, H. K. Versteeg, G. Hargrave, B. Myatt, D. Lewis, T. Church & G. Brambilla. (online 2017). 'Transient flashing propellant flow models to predict internal flow characteristics, spray velocity, and aerosol droplet size of a pMDI' Aerosol Science and Technology
- B Myatt, D Lewis, T Church, G Brambilla, GK Hargrave, HK Versteeg, EJ Long, B Gavtash (2015) 'PDA Analysis of HFA/Ethanol pMDI Aerosols: An Improved Test Protocol and New Findings', ICLASS 2015, Tainan, Taiwan, August 23~27, 2015.
- Myatt, B., Newton, R., Lewis, D. Church, T., Brambilla, G., Hargrave, G., Versteeg, H., Gavtash, B., Long, E. (2015), "PDA and High Speed Image Analysis of HFA/Ethanol pMDI Aerosols: New Findings' Drug Delivery to the Lungs 26, pp. 74 - 77.
- Gavtash, B., Myatt, B., O'Shea, H., Mason, F., Lewis, D., Church, T., Versteeg, H.K., Hargrave, G., Brambilla, G. (2015), "Saturated vapour pressure (SVP) measurement of Ethanol/HFA binary mixtures' Drug Delivery to the Lungs 26, pp. 354 – 357.
- Gavtash, G., Versteeg, H.K., Hargrave, G., Lewis, D., Church, T., Brambilla, G., Myatt, B., O'Shea, H., Mason, F., (2015), 'CFD Simulation of pMDI Aerosols in confined geometry of USP-IP using predictive spray source' Drug Delivery to the Lungs 26, 211 - 214.
- F Mason, D A Lewis and B.Gavtash. 'Empirical Equations for Predicting the Vapour Pressure of HFA 134a or HFA 227ea Systems containing Ethanol' Drug Delivery to the Lungs 11-13th Dec 2013.

2013 – 2016: Ben Myatt, “A Study of Primary Atomisation and Aerosol Plume Transport of a Pressurised Metered Dose Inhaler”, Wolfson School of Mechanical and Manufacturing Engineering, Loughborough University.

Deliverables:

- Versteeg H, Hargrave GK, Myatt BJ, Lewis D, Church T, Brambilla G, (2017) Using Phase Doppler Anemometry & High Speed Imaging to Analyze MDI Spray Plume Dynamics (accepted for publication), RDD Europe, Nice.
- B. Gavtash, H. K. Versteeg, G. Hargrave, B. Myatt, D. Lewis, T. Church & G. Brambilla. (online 2017). 'Transient flashing propellant flow models to predict internal flow characteristics, spray velocity, and aerosol droplet size of a pMDI' Aerosol Science and Technology
- B Myatt, D Lewis, T Church, G Brambilla, GK Hargrave, HK Versteeg, EJ Long, B Gavtash (2015) 'PDA Analysis of HFA/Ethanol pMDI Aerosols: An Improved Test Protocol and New Findings', ICLASS 2015, Tainan, Taiwan, August 23~27, 2015.
- Myatt, B., Newton, R., Lewis, D. Church, T., Brambilla, G., Hargrave, G., Versteeg, H., Gavtash, B., Long, E. (2015), "PDA and High Speed Image Analysis of HFA/Ethanol pMDI Aerosols: New Findings' Drug Delivery to the Lungs 26, pp. 74 - 77.
- Gavtash, B., Myatt, B., O'Shea, H., Mason, F., Lewis, D., Church, T., Versteeg, H.K.,

Hargrave, G., Brambilla, G. (2015), 'Saturated vapour pressure (SVP) measurement of Ethanol/HFA binary mixtures' Drug Delivery to the Lungs 26, pp. 354 – 357.

- Gavtash, G., Versteeg, H.K., Hargrave, G., Lewis, D., Church, T., Brambilla, G., Myatt, B., O'Shea, H., Mason, F., (2015), 'CFD Simulation of pMDI Aerosols in confined geometry of USP-IP using predictive spray source' Drug Delivery to the Lungs 26, 211 - 214.

2014 – 2020: Stewart Yeung, "Limitations of high dose carrier based formulations", Sydney Medical School, University of Sydney.

Deliverables:

- Yeung S., Traini D., Tweedie A., Lewis D., Church T. and Young P.M., (2018) 'Limitations of high dose carrier based formulations. Int. J Pharm; 544(1):141-152.
- Yeung S., Traini D., Tweedie A., Lewis D., Church T. and Young P.M., (2018) 'Dosing challenges in respiratory therapies'. Int. J Pharm; 548(1): 659-671.
- Yeung S., Traini D., Tweedie A., Lewis D., Church T., Young P.M. (2018) 'Aerosol Performance of High Dose Dry Inhalation Dry Powders with Two Dosing Cup Sizes' CRA 2018

2016 – 2020: Nazli Nezami, "A study of factors affecting cavitation and bubble formation in HFA propellants", Wolfson School of Mechanical and Manufacturing Engineering, Loughborough University.

2015 – 2020: Tim Rouse, "To Design and Discover the Perfect Particle for Dry Powder Inhalers" Bath University.

Deliverables:

- Rouse T., Price R., Shur J., Marriner-Edwards C., Lewis D.A., (2017) 'Use Of 3D Printing As A Tool For Fundamental Inhaled Research' AAPS, 12-15 Nov 2017, San Diego Convention Centre

ICASE 4 year post-doctoral programme: 2016 - 2020; "Mechanisms of sugar alcohol effects on respiratory membrane biophysics", awarded in conjunction with Professor Ben Forbes and Dr Richard Harvey at the Institute of Pharmaceutical Science, Kings College London.

2015 – 2020: Precious Akhuemokhan; "The Influence of Non-volatile Excipients on pMDI Aerosol Biopharmaceutics:"

2016 – 2020: Wachirun Terakosolphan; "The influence of non-volatile excipients on pMDI aerosol biopharmaceutics: in vivo studies"

Deliverables:

- Terakosolphan W., Malmlöf M., Lewis D., Forbes B., (2017) "The effect of glycerol on the formation of drug particles emitted from solution-based pressurised metered dose inhalers (pMDIs) using different testing apparatus', Drug Delivery to the Lungs 2017

2015 – 2021: Natalie Armstrong-Green 'Inhalation Aerosol and Response to Humidity', University of Bristol partially funded by the EPSRC Institutional Sponsorship funding

Patents:

135. TNSN98087 (A1), 2000, Pharmaceutical aerosol compositions
136. ITMI991712 (A1), 2001, New pressured metered dose inhalers (MDI) in which all the internal surfaces of the inhalers are stainless steel, anodised aluminium or are lined with an inert organic coating are new
137. ZA200104222 (A), 2002, pressurised metered dose inhalers (mdi)

138. AR021391 (A1), 2002, pressurised metered dose inhalers (mdi)
139. WO02072448 (A1), 2002, inhaler with means for improving chemical stability of medicinal aerosol solution contained therein
140. EP 1321159 A1, 2003, Pressurized metered dose inhaler (pMDI) actuators with laser drilled orifices
141. TNSN01071 (A1), 2003, FORMULATIONS CONTAINING A GLUCOCORTICOID DRUG FOR THE TREATMENT OF BRONCHOPULMONARY DISEASES
142. US2003157028 (A1), 2003, formulations containing an anticholinergic drug for the treatment of chronic obstructive pulmonary disease
143. US2003178022 (A1), 2003, pressurized metered dose inhaler (pmdi) actuators and medicinal aerosol solution formulation products comprising these actuators
144. NO20034873 (A), 2003, solution aerosol formulation containing esters of 3, 17-dihydroxy oestratriene derivatives for pulmonary delivery
145. WO 2003074025 A2 , 2003, Pressurised metered dose inhalers containing solutions of beta-2 agonists
146. AU774250 (B2), 2004, pharmaceutical aerosol composition
147. US2004184993 (A1), 2004, pharmaceutical aerosol composition containing hfa 227 and hfa 134a
148. US7381402B2 (2004), Stable pharmaceutical solution formulations for pressurized metered dose inhalers
149. EP1480615 (A1), 2004, Formoterol Superfine Formulation
150. EP1480617 (A2), 2004, pressurised metered dose inhalers containing solutions of beta-2 agonists
151. MA26898 (A1), 2004, formulations pharmaceutiques stables en solutions pour inhalateurs sous pression a comptage de dose.
152. EP1415647 (A1), 2004, Long-acting beta-2 agonists ultrafine formulations
153. GEP20053649 (B), 2005, stable pharmaceutical solution formulations for pressurised metered dose inhalers
154. US2006120966 (A1), 2006, salmeterol superfine formulation
155. US2006165603 (A1), 2006, solubilisation of drugs in hfa propellant by means of emulsions
156. EP1715849 (A1), 2006, stable pharmaceutical solution formulation for pressurized metered dose inhalers
157. GEP20063985 (B), 2006, aerosol formulations for pulmonary administration of medicaments to produce a systemic effect
158. GEP20064002 (B), 2006, metered dose inhaler
159. EP 1787639 A2, 2007, Stable pharmaceutical solution formulations for pressurised metered dose inhalers
160. SI1133277 (T1), 2007, pharmaceutical aerosol composition containing hfa 227 and hfa 134a
161. HK1182033 (A1) 2010, Metered-dose Inhaler Actuator, Metered dose inhaler
162. CA2856028C (2011), Method and system for electronic mdi model
163. US10737044B2 (2012), Aerosol inhalation device
164. RU2013115273 (A), 2014, dosing inhaler and method of thereof application
165. SG11201501434P (A), 2015, aerosol inhalation device
166. RU2013115274 (A), 2014, actuating mechanism of dosing inhaler and dosing inhaler
167. HK1200127 (A1), 2015, method and system for electronic mdi model mdi
168. TN2015000073 (A1), 2016, AEROSOL INHALATION DEVICE
169. CN105854136 (A) , 2016, Metered-dose inhaler and method of using the same